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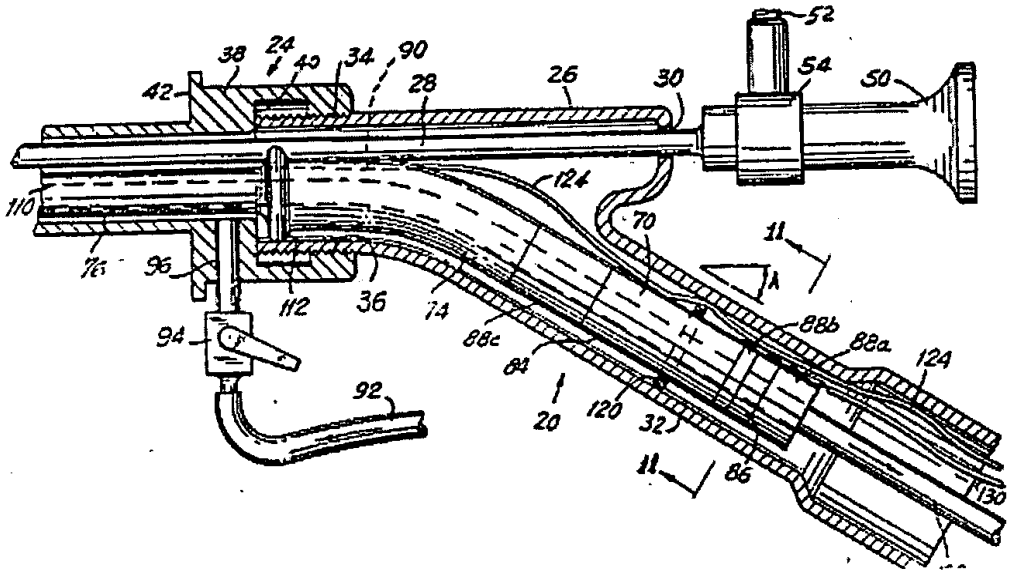

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Method for removing cellular material with endoscopic ultrasonic (^) aspirator

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Abstract: A method and apparatus for endoscopic removal of compliant biological tissues utilizing an endoscopic ultrasonic (^) aspirator comprising irrigation and aspiration means, a piezoelectric ultrasonic (^) transducer, a first resonator such as a half-wave stepped velocity transformer, a probe including a second resonator such as a constant- stress velocity transformer, a blunt or modified working tip of open channel means or restricted tubular means for application of ultrasonic (^) energy to cellular material, and a capacitive fluid sensor to detect the presence of irrigation fluid adjacent these transformers within the instrument. The surgery is advantageously performed by operating the transducer in the 10-20 kHz range to achieve maximum cavitation of the intracellular fluids in the tissues to be removed.

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US Patents Cited: Re30536 2227727 2514080 2714890 2723386 2845072 2874470 2990616 3027690 3065749 3075288 3076904 3086288 3089790 3109426 3113225 3133351 3149633 3166840 3213537 3368280 3375583 3380446 3433226 3526219 3546498 3565062 3589363 3636947 3693613 3805787 3823717 3902495 3941122 3956826 4016882 4041947 4063557 4136700 4146019 4223676 4425115 4493694 4516398 4689040

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Background and Summary

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to a method and apparatus for removing unwanted biological tissue. It relates more particularly to surgery using an endoscopic **ultrasonic (^)** aspirator with an elongated hollow probe and simultaneous irrigation and aspiration, which disintegrates and removes highly compliant tissue from deep within the body through a narrow **surgical (^)** orifice.

2. Description of Related Art

The endoscopic **ultrasonic (^)** aspirator (hereinafter "EUA") of the present invention is particularly useful in the field of transurethral resection (TUR) of the prostate gland or other urological surgery, including destruction and removal of bladder stones. More generally, it is useful in any type of surgery in which deep penetration of the body through a narrow orifice is required, for example arthroscopic surgery, diskectomy, or other orthopedic surgery.

In a preferred embodiment of the invention, an **ultrasonic (^)** probe with a high peak tip velocity is insertable at least about 19 cm into the body for disintegrating compliant tissues, simultaneously irrigating the operating site, and aspirating fluid and tissue, through a **surgical (^)** orifice no more than about 29 mm in circumference, which is the accepted maximum dimension for an instrument to be inserted into the urethra. The circumference of the instrument may be as great as about 29 mm, but preferably is no more than about 25 mm.

A unit of measurement known as the French is frequently used to denote circumferential size. A sheath size in French is three times the sheath's diameter in millimeters. Thus, a sheath having a circumference of 30 mm has a diameter of 30 /.pi.=9.55 and a French size of 9.55.times. 3=28.65.

Since the 1950's TUR has been the procedure of choice for removal of the diseased prostate gland. In one conventional procedure, the patient is placed in the conventional lithotomy position under spinal anesthesia. An elongated resectoscope with a light source, a telescope, a cutting electrode, and a source of continuous irrigation is inserted into the urethra and advanced to the vicinity of the prostate gland, where access to the prostate is gained through the urethral wall. The cutting electrode is a semicircular wire mounted at the end of a slidable shaft for antegrade and retrograde motion; that is, toward the front and rear of the patient. The electrode is supplied with a pulsed RF current which both cuts and cauterizes tissue. The shaft is spring- biased toward the rear of the patient and is repetitively drawn forward by a trigger-like lever as the electrode slices off small slivers of prostate tissue.

As the tissue is sliced off it is washed into the bladder by the continuous irrigation, which fills the bladder about every 5 minutes. The accumulated water and debris must be removed periodically with a suction device such as the Ellik evacuator, which has a squeeze bulb coupled to a flexible plastic catheter. The resectoscope is removed, the bulb is compressed and the plastic catheter is inserted to the operative site. Then the bulb is expanded to draw out the water and tissue debris.

This traditional procedure has a number of disadvantages that the present invention is intended to avoid. In order for the surgeon to view the operating site, the EUA must be provided with some type of viewing and lighting system. It has been found that, at the present level of optical technology, an adequate endoscopic view of **surgical (^)** procedures requires an optical relay lens system that uses lenses with a diameter of about 2.5 mm. Since these lenses must be mounted within a rigid tube that also contains illumination fibers, the total diameter of the finished telescope typically measures about 4 mm. Additionally, in order for a hollow **ultrasonic (^)** tip to remove firm prostatic tissue at an adequate rate (typically from about 5 to about 10 grams per minute), the bore of the tip must also be about 4 mm.

In an endoscopic aspirator, both the telescope and the tip are placed side by side within a sheath. When the endoscopic aspirator is inserted into a patient's body, the sheath protects the surrounding tissue from contacting the **ultrasonic (^)** tip which vibrates not only at its **surgical (^)** extremity but also along its entire length.

The use of a loop-shaped electrode for cutting requires antegrade cutting so that removed tissue does not

build up in front of the loop and block the viewing lens. However, with antegrade cutting, the loop is always hidden under some thickness of tissue. This leads to the risk that the surgeon's view will be blocked and the urinary sphincter, the bladder wall, or even the intestines may be accidentally damaged. The surgeon can also pierce the prostate capsule, which is the tougher outer skin of the prostate, and injure the blood vessels beyond. Electrical cutting is very fast, so that can occur even with the exercise of due care. Further when the telescope of the EUA is positioned adjacent to the **ultrasonic (^)** tip, the walls of the **ultrasonic (^)** tip interfere with the surgeon's view of the operating site.

Also, evacuation must be performed 10 to 20 times, removing the resectoscope each time, and this may take up as much as 20 to 50 percent of the one-hour operating time.

Another disadvantage of the prior procedure is that the continuous irrigation flow described above causes filling and distention of the bladder and absorption of the fluid into the blood, leading to the danger of hypervolemia or hyponatremia. Also, electrical cutting requires the use of a relatively expensive non-conducting fluid medium such as isotonic glycine. If a conducting fluid such as saline is used, the cutting current can be short-circuited away from the work. The fluid must be isotonic to avoid intravascular hemolysis.

Further, the prior procedure is incapable of removing bladder stones, which may necessitate two operations where a single operation would have been preferable.

Since the EUA is frequently used in the field of transurethral resection, the EUA must frequently be inserted into the urethra. Therefore, the circumferential size of the sheath of the EUA is limited by the elastic extension of the urethra which is typically about 30 mm (or about 28 French). Surgeons, however, prefer to use sheaths of smaller size, such as 24 or 25 French, to avoid the occurrence of strictures or contractions of the urethra following excessive endoscopic dilation.

Endoscopic **ultrasonic (^)** tissue removal and aspiration avoids these disadvant ages. **Ultrasonic (^)** tissue removal has been employed in the past for dissection and removal of biological tissue. However, no **ultrasonic (^)** instrument has been available to remove highly compliant tissues through a narrow orifice, for example in transurethral prostate resection. The prior art has two principal failings. First, there was no long, slender probe capable of sustaining **ultrasonic (^)** vibrations at the high tip velocities that are necessary for removal of such tissues. Second, the art has not realized that the most efficient tissue removal is by **ultrasonic (^)** vibrations causing cavitation of the fluid within the cells. Such vibrations should preferably be in the 10-20 kHz range, although other frequencies may be used. The term "**ultrasonic (^)**" will be employed herein to refer to all the frequencies of interest, including some frequencies in the audible range.

In one early development, Von Ardenne and Grossman reported in 1960 on the use of **ultrasonic (^)** vibration to assist in inserting small- gauge wire probes and hollow needles into the skin. They mention constructing an ultrasonically vibrating needle connected to a syringe which is adapted to inject or withdraw fluid or other material from adjacent the tip of the needle. They employ a velocity transformer of the exponential type and operate at a frequency of about 25 kHz with a tip excursion of about 10-100 microns.

Also in 1960, Watkins et al. reported the use of an **ultrasonic (^)** chisel to fracture and remove calcium deposits from cardiac valves. The authors state that their technique is unusable on soft, flexible tissues since the belief at the time was that such tissues are relatively undisturbed by **ultrasonic (^)** vibration. Their apparatus operates at about 26.5 kHz with a tip excursion of about 38 microns.

Ultrasonic (^) energy has also been employed to cavitate a liquid medium to burst and destroy suspended

microorganisms for either sterilization or extraction of the protoplasm. This technique typically employs a solid round metal horn immersed in the liquid medium and vibrating at perhaps 20 kHz with a stroke of about 20-40 microns. It operates by cavitating the water around the cells, rather than the intracellular water.

Prior patents have disclosed **surgical (^)** instruments in which ultrasonically vibrating tools remove unwanted biological material while providing irrigation of the work area and aspiration of fluids and removed material. See, for example, U.S. Pat. No. 2,874,470 to Richards, U.S. Pat. No. 3,526,219 to Balamuth, U.S. Pat. No. 3,589,363 to Banko and Kelman, and U.S. Pat. No. 4,063,557 to Wuchinich et al. The Richards device is a dental instrument which operates above the audible range, preferably at about 25 kHz, with an amplitude of about 10 microns. In the Balamuth '219 device, a sharp-edged tool vibrating at about 25 kHz directly contacts tissue to "chop" it. In the Banko and Kelman '363 device, a thin-walled tubular tip which vibrates with an amplitude of about 50-70 microns breaks apart and removes relatively hard biological material such as cataract material in the lens of the human eye. The Wuchinich et al. '557 patent discloses a device for removing compliant tissues such as neurological neoplasms, employing a magnetostrictive transducer which vibrates at about 25 kHz with a stroke of about 25 microns. A stepped and tapered mechanical transformer increases the stroke to about 125-400 microns.

None of these devices has been capable of providing sufficient tip velocity and a long and narrow enough probe to perform endoscopic surgery. The greatest insertable distance available with prior **ultrasonic surgical (^)** instruments has been about 7-8 cm. More particularly, prior devices have been unable to exert sufficient sound pressure on compliant cells in a biological tissue structure such as a glandular tumor to produce cavitation in the intracellular fluids of the cells, or to disintegrate them in any fashion.

SUMMARY OF THE INVENTION

The prior art devices being ineffective, it was desired to improve the speed and efficiency of tissue removal, and provide a vibrating probe longer and faster than was previously available for endoscopic surgery.

Experiments by the inventors have shown that the effectiveness of **ultrasonic (^)** vibration on biological tissues is related to the water content of the tissue. Tissues that have been allowed to dehydrate are much less amenable to attack and removal by vibration than those that are fresh or have been kept moist. It has also been seen that the walls of blood vessels or the connective tissue overlying muscles and brain tumors are not affected by an ultrasonically vibrating tool nearly as much as soft, fleshy specimens such as neoplasms, or muscle tissue. Since the intracellular water content of the unaffected tissues is much lower than that of the tissues that are affected to a greater extent, this "tissue-differential" or "tissue-selective" effect seems to be related to the water content of tissue.

The present inventors conceived that the tissue-differential effect could give **ultrasonic (^)** aspiration a unique advantage in endoscopic surgery, since the undesired tissue could be removed without risking injury to other structures under difficult conditions of visibility and access to the operating site.

Because of the relationship between tissue removal and water content, the inventors hypothesized that the physical mechanism causing the parting of tissue was the destructive effect of intracellular cavitation, i.e., the formation, due to rapidly varying pressure, of microscopic vapor bubbles in the intracellular fluids. For a given level of pressure in a fluid, the degree of cavitation is determined by a number of the fluid's physical properties, for example temperature, surface tension, viscosity, vapor pressure and density. Very important is the dependence of cavitation upon (1) the applied pressure, and (2) the frequency at which the applied pressure oscillates. Studies have suggested that the intensity of cavitation in water increases as the frequency of vibration is lowered. This hypothesis was tested by setting up two transducer tips having exactly the same size but providing different frequencies of pressure oscillation. Since the pressure

produced by oscillating motion is proportional to the velocity of this motion, both tips were operated with the same velocity at the point of tissue contact. One tip vibrated at 40 kHz, while the other vibrated at 20 kHz. On the same specimen, the use of 20 kHz vibration approximately doubled the rate of tissue removal--confirming a relation to cavitation, and disproving any suggestion that tissue fragmentation could be enhanced only by increasing vibrational amplitude or acceleration. Similarly, it was found that the cavitation rate again doubles when the frequency is further lowered to 10 kHz. Below a threshold of 10 kHz, the rate remains constant.

There is also a pressure threshold, below which it is not possible to cavitate a given fluid. This threshold also decreases with frequency down to about 10 kHz, below which the pressure threshold does not decrease further.

For these reasons, the frequency regime preferably embraced by this invention extends from 10 kHz to 20 kHz, and thus encompasses part of the aural spectrum, although of course lower or higher frequencies could be used. It was previously assumed that the use of audible frequencies would be irritating and dangerous to the surgeon and that the frequency should be restricted to the inaudible range above 18 kHz. Longer wavelengths were also discouraged because a half-wavelength transducer at 20 kHz would be about 5 inches long, approximately the maximum length for convenient hand-held use.

However, the present inventors have found that in an endoscopic device different considerations apply than those previously known to the art. In endoscopic surgery most of the vibrating components are placed within a natural body orifice, such as the urethra, so that the radiation of aural sound is greatly damped by the intervening body tissues. In some percutaneous applications, such as arthroscopic surgery, while only part of the instrument may be placed within tissue, the sound radiated from the exposed parts is minimal and can be effectively limited if desired by the use of absorbing sheaths and enclosures over the transducer and a portion of the tip.

Even with the use of the most advantageous frequencies, the maximum possible tip velocity should also be employed to further enhance pressure and hence cavitation. Since pressure is related to the velocity of the transducer by the conventional formula P=ZV, where Z is the acoustic impedance of the fluid, the relationship between cavitation and pressure translates into a direct dependence of cavitation upon velocity. Cavitation is believed to be relatively independent of both the acceleration and the amplitude of vibration.

Velocity cannot be increased without limit, however, since there is a definite physical limit to the velocity at which robes or tips made out of known materials can be safely vibrated. The mechanical stress at a given point within a vibrating tip is directly related to the tip velocity at that point. Increasing the tip velocity correspondingly increases the stress within the tip until it exceeds the strength of the crystalline bonds within the tip material and the tip fractures. Special designs can be developed to permit great tip velocities for a given maximum stress, but prior art designs have invariably increased the cross-sectional size of the tip and have been difficult to fabricate. Therefore, in addition to lowering the frequency of vibration, an important object of the invention is also to increase the cavitation rate by providing improved apparatus to enhance the available tip velocity without exceeding the maximum permissible stress on the tip material.

For a regular structure, such as a tube with constant cross- section, the tip velocity at a given point is related to stress according to the equation s=pcv, where v is the velocity (distance per unit time), p is the density of the material of which the tip is made (mass per unit volume), c is the velocity with which extensional sound waves travel in the tip (distance per unit time) and s is the stress is the tip (force per unit area). For titanium, which is capable of bearing the greatest stress of any commonly available material, the above relation means that maximum permissible velocity is approximately 1270 centimeters per second. However, it is known that effective removal of living tissue preferably employs velocities of at least about 2540 centimeters per second.

To improve tissue removal, greater tip velocity may be obtained by use of a velocity transformer having non-uniform cross-section. The equation above applies only to uniform structures, such as tubes having a constant cross-sectional area. If the tube is made non-uniform, the equation is modified by a shape factor M, sometimes called a figure of merit: ##EQU1## Depending upon how the alteration is made, the shape factor either increases or decreases the available tip velocity for a given maximum stress. Of interest here is finding a tip design whose shape factor is greater than one.

It is clear from the modified equation that for a given maximum allowable stress, the tip velocity may be increased over that obtainable in a uniform tube by a factor of M.

There are a variety of tip designs in which the tip's cross- sectional area varies with respect to its length to provide a value of M that is substantially greater than one. For example, exponential tips whose cross-sectional area varies along its length as

Area=A.sub.o e.sup.-aL

where e is the natural base, Ao and a are constants and L is the distance from the point in question to the end of the tip, can theoretically provide a shape factor equal to e or 2.7. However, to obtain this value of M requires that the tip begin and end with drastically different diameters. A tissue removal device employing an exponential design with a shape factor of 2, which could safely produce a tip velocity of 25.4 m/sec, would begin with a diameter roughly five times that of the **surgical (^)** end. In an endoscopic device that must extend several inches into a narrow body orifice, an exponential design is impractical. If built to accommodate the limitations of human anatomy, its tip would be too small to remove tissue at a practical rate.

It has been found that the most space-efficient design for increasing the value of M from 1 to approximately 2 employs the use of a constant-stress velocity transformer coupled to a constant-diameter velocity transformer. In a uniform tube executing extensional vibration, the stress obeys the relation

s=sin .pi.x/L

where x is the distance to the point in question from one end of the tube, and L is the total length of the tube. It can be seen from this relation that the stress is maximum when x=L/2. Thus it would be desirable to provide at the working end of a **surgical (^)** probe having length L/2 a further section with varying cross-sectional area, so that for values of x greater than L/2 the stress will remain constant at the maximum permissible value.

Also, such a design would produce the greatest possible extension for a given maximum stress. Since Hooke's law dictates that the extension of each portion of the transformer is proportional to stress, and since the stress is constant, the extension linearly increases along the tip length beyond its midpoint.

It will be shown below that such a tip, in the region designed for constant stress, has a cross-sectional area obeying the relation

Area=Be.sup.-by2

where B and b are constants and y is the distance from a given point to the end of the tip. This mathematical function is known as the Gaussian function, after the mathematician Gauss who studied its properties. Consequently, the constant-stress tip will be referred to as a Gaussian resonator. Gaussian resonators provide a significant improvement over any alternative design since they can be made with

diameters that can be accommodated by the human anatomy with a sufficiently large tissue contact area and aspiration port to permit efficacious tissue removal, and can exhibit a shape factor of 2, making it possible to practically attain a velocity of 25.4 meters per second in an endoscopic or percutaneous device. Further, the Gaussian design does not require a wide disparity between the two end diameters.

The cross-sectional area progressively decreases along the length of the resonator so as to keep the stress constant, but it need not do so very close to the tissue-containing end of the tip. Since there is no load on this point, the stress is zero, so the very end of the tip need not be designed to sustain the same stress but rather may be contoured and rounded to gradually lower the stress to a value of zero.

The mathematical basis for providing a Gaussian resonator in the EUA is as follows: well-established acoustical principles establish the parameters that affect the maximum velocity available from slender bars undergoing simple extensional vibration. For a uniform bar, with both ends free, the maximum obtainable velocity is directly related to the maximum stress that the material of which the bar is made can safely withstand: ##EQU2## where V.sub.max is the velocity (distance per unit time), S.sub.max is the safe stress limit (force per unit area), p is the material density (mass per unit volume), and c is the velocity with which extensional waves travel in the material (distance per unit time). Since metals are the only practical materials capable of sustaining the high-level acoustic vibration of interest, and since c is approximately the same for all these metals, to obtain the largest possible value of V. sub.max, a material should be selected that has the highest possible strength-to-weight ratio (S.sub.max /P). This material has been well established to be aircraft titanium. The safe value of vibrational stress has been determined by experimentation to be one-third the value of the yield stress (the stress at which the metal begins to irreversibly deform). When V.sub.max is computed using the appropriate values of S.sub.max, p and c, it is found that

V.sub.max =1219 cm/sec. (2)

for a uniform bar of aircraft titanium.

However, this velocity provides only a small degree of soft tissue dissection, even when the frequency of vibration is lowered to enhance cavitation of intracellular water. A value approximately twice that given by Eq. 2 is desirable to effectively disintegrate such tissue. Consequently a velocity transformer is desirable that approximately doubles the value of V.sub.max without increasing the maximum stress above S.sub.max. It is also desirable, in an endoscopic device, for this velocity transformation to be accomplished within a narrow circular channel preferably about 8 millimeters in diameter, of which about 4 millimeters constitutes a circular aspiration bore. It is therefore important that the velocity be increased with a minimum change in cross- sectional area so that the entire resonator can be placed within the endoscope over a length of at least about 17-19 centimeters.

FIG. 1 shows a hypothetical velocity transformer consisting of a uniform section one-quarter wavelength long, followed by an integral second section of length L. FIG. 2 illustrates various possible stress distributions in this bar for different hypothetical cross-sectional variations of the second section. The velocity at any point to the right of the uniform section can be written as ##EQU3## where s(x=o)=S.sub.max, S(x=L)=0, f is the frequency of vibration (cycles per unit of time), and E is the elastic constant or Young's Modulus (force per unit area). Thus, the velocity distribution along the section can be computed directly from these stress distributions. The velocity at any point is proportional to the area under the stress curves to that point. FIG. 3 illustrates these corresponding velocity distributions. Curve 1, although it produces the largest end velocity, exceeds S.sub.max and therefore is not a practical choice. Curves 2 and 3 produce safe stress distributions, but do not result in the maximum attainable end velocity. The areas under these curves in FIG. 2 are less than the areas under curves 1 and 4.

Curve 4 alone increases the velocity most rapidly while maintaining a safe operating stress. Curve 4 represents a constant stress level in the section, except at the terminus, which is free and therefore is not subject to any force.

It remains to be determined how to contour the second section so as to produce this optimum stress distribution. The velocity distribution in an extensionally vibrating slender bar is related to the stress and cross-sectional area as ##EQU4## then v(x) and s(x) are related by Eq. 3 with s(x)=S.sub.max, which results in ##EQU5## Substituting Eqs. 5, 6 and 7 in Eq. 4, there results the condition: ##EQU6## which, when integrated between A(x=o)=A.sub.o and A(x), and between x=o and x=x, yields

A(x)=A.sub.o e.sup.(-k.spsp.2.sup.x.spsp.2.sup./2),0.ltoreq.x. ltoreq.L, where k.sup.2 =[2.pi.f/c].sup.2. (9)

Thus, to obtain the optimal velocity transformation, the cross- sectional area of the resonator must progressively decrease from its value at x=0 as dictated by Eq. 9, which is the Gaussian function.

There is no theoretical limit to the amount the velocity may increase so long as A(x) satisfies Eq. 9. As a practical matter, the resonator is hollow, and ultimately the wall thickness required for ever- diminishing values of A would produce a structure insufficiently strong for the rigors of **medical (^)** use. However, the Gaussian resonator does exhibit a velocity transformation factor of at least 2 with an acceptable starting cross-sectional area A.sub.o, making practical the attainment of tissue dissection with an endoscopic device.

Constant-stress amplification can also be achieved in a uniform structure such as a cylindrical tube by varying the elastic constant E, or both the elastic constant E and the density p, over the length of the structure, without varying the cross-sectional area.

An example is a system is which density is proportional to the elastic constant, that is, p=nE where n is a constant. It is found that constant stress can be obtained in such a system if E is varied according to the Gaussian function:

E+E.sub.o e.sup.-n (2.pi.fx)2/2, (10)

where E(x=0)=Eo. Thus, the elastic constant E decreases from the vibration input to the free end of the resonator. Under these conditions, ##EQU7## Since S(x)=S.sub.max in a constant-stress system, ##EQU8## Since E(x) is a decreasing function, the integral in Equation (12) increases at a faster rate than it would if E(x) were a constant function as in Equation (3) above, so greater velocity amplification can be expected under these conditions than in a system in which cross- sectional area is varied to achieve constant-stress conditions.

According to one aspect of the invention, high-frequency vibration apparatus comprises a vibration source, for vibrating with a first amplitude, a first transformer for amplifying the vibrations, and a second transformer for amplifying the vibrations of the first transformer, the second transformer being elongated and when vibrating having a substantially constant mechanical stress level in substantially all of its length. The second transformer may have a cross-sectional area that varies from its input end to its output end so as to provide such substantially constant mechanical stress level. The cross-sectional area of the second transformer may vary according to the Gaussian function. Alternatively, the substantially constant stress level may be provided without varying the cross-sectional area by varying the elastic constant of the material of the transformer, or both the elastic constant and density of the material.

A further form of the invention includes a handpiece, a vibration source for vibrating with a selected wavelength and with a first amplitude, a first transformer for amplifying vibrations from the vibration

source, and a second transformer for amplifying vibrations from the first transformer, the first transformer having an input section relatively large in cross-sectional area and coupled to the vibration source, and also having an output section, and the second transformer having an input end coupled to the output section of the first transformer, and having an output end vibrating in response to such received vibrations.

According to a further form of the invention, an endoscopic ultrasonic (^) aspirator comprises a hollow handpiece, an elongated sheath having a hollow bore running from the interior of the handpiece to a working end away from the handpiece, a vibration source powered by alternating current, an elongated tool coupled to the vibration source and passing through the hollow bore of the sheath to a work site for transmitting such vibrations, viewing means extending from the handpiece to the work site, means for supplying fluid to a fluid space between the tool means and the hollow bore of the sheath, and fluid detection means for detecting the presence of fluid in the fluid space and terminating the supply of alternating current to stop the vibrations when such fluid is not present.

In another form of the invention, an apparatus for removal of unwanted biological material comprises a handpiece; an elongated sheath extending from the handpiece and having a hollow bore; a vibration source in the handpiece; first and second transformers in the hollow bore for amplifying vibrations from the source to a sufficient velocity to disintegrate unwanted tissue, the vibration means and the two transformers being elongated and having a continuous hollow bore extending along a common longitudinal axis to form (1) a first fluid passage in a space defined between the transformers and the sheath, and (2) a second fluid passage along the common longitudinal axis; means for introducing fluid into one of the fluid passages to irrigate an operating site adjacent a working tip of the second transformer; and means for applying suction to the other of the fluid passages to remove such fluid and such disintegrated unwanted tissue from the operating site. According to a further aspect, the means for applying suction includes a biopsy valve coupled to the fluid passage to which suction is applied for selectively diverting fluid and tissue therefrom, and trap means for receiving and filtering the desired fluid and tissue that has been selectively diverted.

A further aspect of the invention is a method for removing cellular material from a compliant tissue relatively deep within a biological body through a narrow orifice, comprising inserting an elongated surgical (^) instrument into the orifice, with a working tip located close to the material to be removed, and vibrating the working tip so as to disintegrate such material. A further method provides removal of cellular material from a compliant issue at an operating site at least about 8 cm deep within a biological body through a narrow orifice, preferably no more than about 29 mm in circumference, comprising inserting a narrow elongated surgical (^) instrument at least about 8 cm deep into the body through the orifice with a working tip of the instrument being located close to the material to be removed, and vibrating the working tip longitudinally so as to produce pressure waves to disintegrate the material. The vibration of the working tip advantageously cavitates the intracellular fluids in such material to destroy its cells. Vibration is preferably at about 10 to 20 kHz, with a longitudinal stroke of at least about 350 microns, Preferably at least about 700 microns; and with a maximum velocity of at least about 1,000 cm per second, preferably at least about 2,000 cm per second.

A further form of the invention is a method of removing cellular material from a compliant tissue at an operating site deep within a biological body through a narrow orifice, including providing a surgical (^) instrument having an elongated sheath at least about 8 cm in length and no more than about 29 mm in circumference, the sheath having a hollow bore; locating an elongated probe within the hollow bore, the probe having a working end projecting beyond the end of the sheath and a hollow bore therethrough, thereby forming a first fluid passage in the space between the probe and the sheath, and a second fluid passage within the probe; inserting the sheath into the body orifice with the working end of the probe close to the material to be removed; introducing a fluid into one of the fluid passages to irrigate the operating site; vibrating the probe longitudinally so as to produce pressure waves sufficient to disintegrate the cells of the material to be removed; and applying suction to the other of the fluid passages to withdraw the fluid

and the matter to be removed from the operating site.

Employing the invention in transurethral resection of the prostate achieves many benefits such as (1) the tissue-differential effect, (2) a thermal cauterization and an absence of necrosis, which should greatly accelerate healing, (3) retrograde motion of the instrument permitting direct visualization of the procedure, (4) capability of removing bladder stones or the like, and (5) reducing the duration (and hence increasing the safety) of the procedure by increasing the tissue removal rate and permitting continuous operation.

The tissue selectivity of the endoscopic **ultrasonic (^)** procedure reduces the risk of piercing the prostate capsule or bladder unless the instrument is forced by the operator. Any obstructions such as blood vessels are easily felt by the operator in that the handpiece is directly mechanically connected with the working tip, leading to an inherently safer procedure that can be used with less training than the prior procedure.

The **ultrasonic (^)** procedure also causes minimal microscopic tissue distortion, allowing more precise histological diagnosis. The aspirated tissue can be diverted quickly to a biopsy trap of the system and removed for analysis. A further advantage is the elimination of electrical currents passing through the patient's body, avoiding the risk of shock effects, burns, or the obturator nerve reflex.

Employing continuous aspiration of the debris and water shortens the operative time to as little as one-half hour. This results in diminished operative bleeding, as well as generally decreasing operative risk to the patient. Further reduction of bleeding results from the cauterization effect of the friction of the moving tip on adjacent tissue.

Also, using **ultrasonic (^)** tissue removal combined with continuous irrigation and aspiration permits retrograde cutting, giving the surgeon better visibility of what lies in the path of the cutting edge. Since the pieces of removed tissue are small they are easily aspirated, permitting the surgeon to take one continuous cut with good visibility for any length of prostate tissue to be removed.

The present invention also relates to an endoscopic **ultrasonic (^)** aspirator with a tip having a reduced circumference which also provides the surgeon using the aspirator with an increased view of the operating site.

The invention further relates to an improvement of an endoscopic **ultrasonic (^)** aspirator of the type which includes a resonator having a vibrating tip for removal of biological material, means for delivering fluid to the tip, means for removing the fluid and removed biological material, and means for viewing the operation of the vibrating tip. This improvement comprises open channel means connected to the resonator tip to facilitate viewing of the tip during use and means for supporting the open channel means and forming a passage to assist in the proper operation of the aspirator as to the removal of the fluid and removed biological material. If desired, the entire length of the resonator can be configured and dimensioned in the form of open channel means so that the viewing means can be partially received, held and supported by the open channel means, thus minimizing the size of the aspirator. Preferably, the open channel support means is a resilient plug and the channel means has a U or V shaped cross section.

According to a preferred embodiment of the present invention, the tubular **ultrasonic (^)** tip of the aspirator is cut open along its length. The telescope is then suspended within the cut-out portion of the tip. The end of the **ultrasonic (^)** tip thus has a U shape in cross-section with the telescope being suspended within the U. As a result, the under- surface of the telescope partially closes off the opening of the U shaped tip so that a cross-section of the opening at the tip near its operational end has a crescent shape.

Because the telescope is partially inserted into the end of the **ultrasonic (^)** tip, the overall circumference of the end of the aspirator of the present invention is less than that of the end of an aspirator in which the

ultrasonic (^) tip is circular in cross-section where the telescope is placed adjacent to the ultrasonic (^) tip. Additionally, since the upper portion of the ultrasonic (^) tip adjacent to the telescope has been removed, the surgeon's view of the operating site is not obstructed by the ultrasonic (^) tip. To ensure that the relative positions of the telescope and the ultrasonic (^) tip do not change, a plug may be inserted between the telescope and the U shaped tip. The ultrasonic (^) tip and plug are then mounted within a sheath or lower lumen which is attached to the upper lumen in which the telescope is mounted.

Other objects, features, and advantages of the invention will be seen in the following detailed description of preferred embodiments, with reference to the accompanying drawings.

Detailed Description

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

FIGS. 4A and 4B show an endoscopic ultrasonic (^) aspirator according to a preferred embodiment of the invention. A handpiece 20 is located at what will be referred to as the rear end of the device. A sheath 22 extends from the handpiece 20 toward what will be referred to as the working end of the device. A stop assembly 24, integral with the sheath 22, couples the handpiece to the sheath. The handpiece is preferably plastic and the stop assembly and sheath are preferably metal. The EUA also includes a straight telescope 28 which runs horizontally from the rear end to the working end of the EUA. A horizontal upper lobe 26 of the handpiece 20 contains an aperture 30 through which the telescope passes to the exterior of the handpiece. The handpiece also has a lower lobe 32 which forms an angle A with the upper lobe 26. Angle A may advantageously be about 20 to 45 degrees, its purpose being to allow various components to be located within the handpiece without interfering with the straight horizontal line of sight occupied by the telescope.

The sheath 22 is assembled to the handpiece 20 by means of a stop assembly 24, which is integral with the sheath 22 at its rear end. The stop assembly 24 is generally cylindrical and has a circular aperture in its rear side with inward-facing threads 34. The handpiece is circular at its forward end and has outward-facing threads 36 which are adapted for screw-mounting in the threads 34 in stop 24. The stop 24 has a forward portion 38 with annular faces 40 and 42 which face rearward and forward, respectively. The handpiece is screwed into the rear aperture 30 of the stop assembly until it comes into contact with the rear face 40. The front face 42 of stop 24 limits the distance to which the working end of the sheath 22 of the EUA can be inserted into a surgical (^) orifice.

The telescope 28 has at its rear end an eyepiece 50 and a cable 52 for supplying electrical energy to an electro-optical light source 54. From the eyepiece the telescope extends forward in a straight line of sight to the working end of the EUA. The design of the telescope is shown in more detail in FIG. 7. The telescope includes a cylindrical lens system 56 which is located adjacent the lower portion of the cylindrical inner surface 58 of the cylindrical telescope 28. In the crescent-shaped space between the inner surface 58 and the lens system are disposed optical fibers 60 which carry light from the light source 54 to the working end of the telescope. Other illumination sources may be provided. In this embodiment, the outside diameter of the telescope 28 is approximately 3-4 mm, and the outside diameter of the lens system 56 is perhaps 1.7-2.7 mm, depending on the size of the overall telescope 28.

Disposed within the handpiece and sheath is a resonator assembly generally designated 68. The resonator assembly 68, which is seen more clearly in FIG. 5, includes a piezoelectric transducer 70; a first velocity transformer 72 having a relatively thick curved input section 74 coupled to the transducer for receiving vibrational energy therefrom, and an integral narrower output section 76 extending forwardly of the input section 74; and, integrally connected to the forward end of the output section 76, a second velocity transformer 78, which extends from the output section 76 to the working end of the EUA and protrudes

slightly beyond the sheath 22. The transducer's length is substantially one-half of the wavelength of the vibrations employed in the device. Thus, the transducer has vibrational antinodes (loops) at its ends and a vibrational node halfway between its ends. The length of the curved input section 74 of the first transformer 72 is one-quarter wavelength; thus, its point of connection with the transducer 70 is an antinode, and the point of connection to the output section 76 is a vibrational node. The length of the output section 76 is one-half wavelength. Thus an antinode is at the center of this section, and a node exists where it is connected to the second velocity transformer 78.

The second transformer 78 is of the Gaussian type described above. As seen in the schematic graph in FIG. 5, there is little longitudinal extension and little stress in the input section 74, because it is relatively massive and a substantial amount of its vibration is flexural. Stress is high at both ends of the output section of the first transformer, but is zero at its center point, which is a vibrational antinode or loop with greatest longitudinal extension. The stress in the output section 76 is at the maximum permissible level for the material and design employed, in other words S.sub.max, as defined above. The Gaussian resonator 78 exhibits constant stress at this same level S.sub. max throughout most of its length, almost to the tip 80 at its working end. The stress near the tip 80 is substantially zero, since there is ordinarily little or no load on the tip.

As seen in FIG. 6, the second transformer 78 and also the output section 76 are not round. Rather, flats are formed in the top and bottom of these members to provide ample water passages without substantially changing their vibratory characteristics. The central bore 110, however, is substantially circular, with an inside diameter of perhaps 4.33 mm (13 French).

The working end 80 need not lie in a vertical plane as shown, but may be angled or otherwise shaped if desired in a particular application.

The combined length of the output section 76 and the second transformer 78 is advantageously about 19 cm. If desired, it could be lengthened by any integral multiple of one-half wavelength, which at about 20 kHz is about 13 cm.

A piezoelectric transducer such as is used herein typically has a maximum vibration amplitude of about 23 microns. At the frequencies of interest, tip vibration at the necessary velocity entails an amplitude of about 350 microns. The resonator assembly 68 provides this 15-fold increase in vibration amplitude.

A groove 90 is formed in the top of the transformer input section 74 and is sized to accommodate the telescope. The groove 90 permits the telescope to be located closely parallel to the transformer sections 76 and 78 within the forward end of the sheath, without interfering with the input section 74, to achieve a compact and narrow sheath.

The letter R in FIG. 5A refers to the radius of curvature of the curved input section 74. This radius must be small enough so that the handpiece is curved far enough below the line of sight of the telescope, desirably at least about 20 degrees, to achieve a compact and easily handled unit. A radius R of about 5 cm advantageously gives an angle of about 40.degree.. At an operating frequency of 20 kHz, 5 cm is about 0.2 times the wavelength. Preferably, the radius R should be no smaller than about 0.1 times the operating wavelength to avoid excessive energy losses. The radius should also be less than about 0.5 times the wavlength in order to give a usable angle of offset of about 20.degree. over the length of the input section 74, which is about 6 cm. The curvature of the input section is not necessarily circular; thus, the radius R as defined herein is an approximation.

FIGS. 5C and 5D show alternate resonator assemblies 68c and 68d. In FIG. 5C, a first transformer 72 is coupled to a transducer 70. As in the previous embodiment, the first transformer is a half-wave stepped

...Coupled to the working end of the first transformer is a second transformer 78c, which has constant cross-sectional area. Velocity amplification is obtained by increasing the elastic constant of the material in the second transformer from its point of connection to the first transformer, to its tip 80c. Optionally, the density of the material of the first transformer may be decreased as a function of distance from the first transformer to the tip.

In the embodiment of FIG. 5D, the same second transformer 78c as just described is employed. However, in this embodiment the first transformer 72d, which is curved as in the previous embodiments, is not a stepped transformer. Rather, velocity amplification in the first transformer is obtained by increasing the elasticity of the material of the first transformer and optionally decreasing the density of the material, as a function of distance from the transducer. As seen in FIG. 5D the transducer 70 and the first transformer are not necessarily required to have the same cross-sectional area at their coupling for sufficient energy transfer to be obtained.

Because of the curvature of the section 74, the transformer sections 74, 76, 78 may undergo a certain small amount of transverse, flexural vibrations. However, any transverse components of vibration in the sections 76 and 78 are damped by the presence of irrigation fluid in the surrounding space 98 within the sheath.

Irrigation fluid is supplied through a hose 92, and is controlled by a valve 94. The irrigation fluid flows through a radical bore 96 in the outer portion of the front section 38 of the stop assembly 24. It then passes into the spaces 98 that surround the resonators 76 and 78 within the sheath. As indicated generally in FIG. 6, the sheath has a generally ovoid cross-section. Its circumference should preferably be approximately 25 mm, about the same as the circumference of a circular instrument 8 mm in diameter, such dimension being known in the field as 24 French. If necessary a circumference of about 29 mm, corresponding to 28 French, may be usable. With 28 French or larger instruments, there is a risk of injury to a narrow orifice such as the urethra. The telescope 28 is disposed in the narrower part of the ovoid sheath 22. It is enclosed by epoxy material or the like running along the inside of the sheath to form a partition 100, which forms a watertight compartment for the telescope.

Irrigation fluid flows toward the working end of the EUA through the space 98 from the vicinity of the stop 24, damping any transverse vibrations of the transformer sections 76 and 78, as well as irrigating an operating site adjacent the tip 80. Auxiliary fluid passages may also be provided. Fluid is prevented from flowing into the handpiece by a sealing ring 112 shown in FIG. 8. The ring is generally O-shaped, but has a smaller aperture formed in its upper portion to accommodate the telescope. The sealing ring 112 seals the annular space surrounding the input transformer section 74 within the handpiece, and provides the hole 114 for water-tight passage of the telescope.

Additional sealing and support is provided by an O-ring 120 disposed about the transducer within the inner wall of the lower handpiece lobe 32. The O-ring 120 is located at the vibrational node at the center of the transducer.

The coupling between the transducer and the input section 74 may advantageously include female threads counterbored into the abutting ends of the aspiration passages 110 of the transducer and the input section, and a hollow threaded stud threaded into both of these. Such a connection allows for a smooth, fine finish the adjacent faces of these two resonator elements, for good acoustic coupling between the faces.

Referring again to FIGS. 4A and 4B, aspiration is provided through a continuous concentric bore 110 extending from the tip 80 through the second transformer 78, the first transformer 72, and the transducer 70 to a hose 122, which is connected to a source of suction. Other passages may be provided as well. By these means, fluid and removed tissue flow from the operative site and are aspirated through the EUA away from the operating site for either disposal or histological analysis.

The edges of the working end of the second transformer 78 at the tip 80 are rounded, in order to provide tissue removal by cavitation of intracellular water, as discussed previously, without allowing indiscriminate cutting by the tip 80, which could inadvertently injure tissues not intended to be removed.

It is important for any transverse vibration components of the transformer section 76 and 78 to be damped by fluid flowing in the spaces 98, and for vibration to terminate if there is no fluid present. For this purpose, a fluid sensor is provided in the form of an insulated wire 124 running rearward along the telescope, and separated from the fluid space 98 by the partition 100. The wire 124 runs through the hole 114 in the sealing ring 112, and through the groove 90 in the input section 74, to the interior of the handpiece. The wire could also be set into a groove either in the partition 100, in the bore that encloses the telescope, or in the bore that encloses the resonators, if desired. It may also be exposed to fluid if appropriate insulation is provided. The wire is fine enough that it does not interfere with the seal provided by the sealing ring 112. The wire 124 then passes around the O-ring 120 to the exterior of the handpiece. As explained further below, means are provided in the high-frequency power supply circuit to sense the capacitance between this wire 124 and the second transformer 78, which is grounded. If the capacitance increases, which indicates the absence of water, then the vibration of the transducer 70 is inhibited to prevent excessive transverse vibrations and possible damage to the resonator components.

FIG. 9 shows elements of an alternate embodiment of the invention. In this embodiment, there is no partition between the telescope 28a and the irrigation-fluid-containing space that encloses the resonators 76a, 78a. To support the telescope, a quantity 82 of biologically inert silicone rubber adhesive or the like is placed between the telescope and the junction of the resonators 76a and 78a. It is important to employ a flexible adhesive to allow some relative motion, even though this junction is a vibrational node, since each point on each resonator is subject to a small degree of radial vibration, which is inherent in a body undergoing extensional vibration. As each incremental section of a resonator is compressed it instantaneously bulges slightly. Thus, each point on each velocity transformer constantly undergoes a slight radial expansion and contraction. These radial vibrations should be isolated from the telescope. However, there cannot be more than about 250-500 microns of separation between the telescope and the resonators because of the severe size limitation on the sheath. This need for proximity, in view of the further need for vibrational isolation, is resolved by connecting the elements with a flexible adhesive.

The ultrasonic (^) generator and related circuitry for powering and controlling the ultrasonic (^) transducer 70 are shown in FIGS. 10A and 10B.

The transducer 70 includes an elongated toroidal piezoelectric crystal 71 that is driven by a cylindrical high-voltage electrode 84 and an annular ground electrode 86. (See also FIGS. 4A and 11.) The ground electrode 86 is electrically connected to a conductive lining 116. The lining 116 runs the length of the transducer 70, lining the aspiration passage 110, and is electrically coupled to the velocity transformers. The transducer is insulated by cylindrical insulators 88a, 88b, 88c located at the ends of the transducer and between the electrodes 84 and 86.

The piezoelectric transducer and tip are driven by the generator through a two-conductor coaxial cable 130. It is energized by an AC signal whose magnitude and frequency are controlled by a DC-to-AC inverter 132. This inverter converts an input DC voltage to an alternating current signal having a frequency controlled by an AC signal supplied to its frequency control input 134 and a magnitude controlled by a DC voltage level supplied to the inverter at its magnitude control input 136. The frequency provided at the input 134 is the frequency at which the transducer is caused to vibrate. The DC voltage supplied at the input 136 is that required to maintain a selected amplitude of vibration at the frequency of vibration.

The exciting frequency and voltage are derived from a feedback signal obtained by adding two signals that

are proportional to the voltage and current input to the transducer. In FIG. 10, C.sub.1 and C. sub.2 form a capacitive voltage divider which produces a voltage across C.sub.2 that is directly proportional to and in phase with the transducer voltage. The voltage across C.sub.3 is proportional to the transducer current, but shifted in phase by 90 degrees. The voltage between the wiper of potentiometer R.sub.1 and ground, which constitutes the sum of these two potentials, is the feedback signal. When R.sub.1 is properly set, the feedback signal is very low at all excitation frequencies except at the resonant frequency of the transducer, since at resonance the transducer voltage and current are 90 degrees out of phase.

At resonance, when the feedback signal is present, its magnitude is proportional to the amplitude of vibration and its phase exactly equals that of the inverter output signal.

The inductance L reactively cancels the transducer's static capacitance; that is, the capacitance of the cable 130 and the net capacitance of the voltage divider C.sub.1,C.sub.2. This capacitance is advantageously neutralized so that the voltage at the wiper of R.sub.1 will be proportional to the vibration amplitude and will be very small at frequencies other than resonance.

The feedback signal is fed to two control loops: one for establishing the correct frequency and the other for establishing the desired vibration amplitude. When the aspirator is de-energized there is of course no feedback signal, and some means of starting vibration has to be provided. A predetermined starting frequency is provided by a voltage-controlled oscillator 140. In the absence of any feedback, this oscillator runs at a frequency adjusted by variable resistor R.sub.3 in the general range of the expected transducer resonance. Since, in general, this initial exciting frequency is not the resonant frequency, a substantial feedback signal will not be produced. However, acoustic resonators do exhibit some greatly diminished level of vibration at frequencies within about five percent of their actual resonance. Therefore, a small, but detectable, feedback signal is produced.

In the frequency control loop, the feedback signal enters a very sensitive phase comparator 142 which produces a DC voltage proportional to the difference between the phase of the feedback signal and the phase of the output of the voltage-controlled oscillator. The frequency of the feedback signal is the same as that of the oscillator, but the phase is not the same because the frequency is not yet at the resonant frequency of the transducer. The output from the phase comparator is greatly amplified by a phase error amplifier 144 and then passed through a limiter 146 which places upper and lower bounds upon the amplifier's output. This amplified signal, subject to the bounds of the limiter, is then supplied to a steering input 148 of the voltage-controlled oscillator 140, and modifies its output frequency until the phase difference between the feedback signal and the output signal of the VCO is minimized. The VCO frequency that produces this result is the actual resonant frequency of the transducer.

The result of limiting the range of the steering voltage applied to the oscillator at input 148 is to limit the extent to which the frequency can be shifted. In general, a complex acoustic resonator, such as transducer 70, has more than one extensional resonance, at only one of which the desired performance is obtained. Excitation at other resonant frequencies would result in much lower vibration levels and very poor tissue dissection. Because the vibration levels are much lower at these parasitic resonances and constitute a lower overall energy of vibration, if precautions were not taken, the system would naturally tend to operate at frequencies where it did less work. The limiter 146 prevents the oscillator from being driven to frequencies hat lie outside a predetermined band which brackets the intended resonance.

n the amplitude control loop, the feedback signal is fed to a rectifier 150 which produces a DC voltage roportional to the magnitude of the feedback signal. A low-pass filter (^) 152 is provided to eliminate any C components and extract only the direct current component. This signal is then subtracted by a summer 54 from a preselected DC voltage. The difference between these two voltages is greatly amplified by an mplitude error amplifier 156 and is input to the main power supply 160 to control its DC output voltage.

This DC output voltage is the source of power to the inverter 132. It is proportional to the magnitude of the inverter's AC output signal, which, in turn, is proportional to the amplitude of vibration of the transducer 70. This amplitude control loop maintains the amplitude of vibration desired by the operator regardless of the power drawn from the inverter 132 by the transducer 70, thereby providing uniform performance in the presence of compliant as well as resistant tissue. Since the power available from the inverter is not limitless, internal circuitry is provided in this component to safely limit the maximum power consumption by the transducer, and thus preclude unsafe power demands through intentional or unintentional abuse. If the power limit of the inverter is reached, the output vibration amplitude is automatically reduced. The amplitude is reestablished at the control setting once the excessive power requirement has been removed.

Also seen in FIG. 10A is a capacitance sensor 162 which measures the capacitance between the capacitance probe 124 and ground. When this capacitance increases substantially, indicating the absence of water surrounding the velocity transformers 72 and 78, the capacitance sensor 162 sets the input level at an input 138 of the inverter 132 to a level that inhibits the inverter and terminates the AC output to the transducer.

FIG. 12 illustrates an overall endoscopic **ultrasonic (^)** aspiration system. An irrigation fluid source 170 is located about 1-2 meters above the EUA. This distance provides sufficient hydrostatic pressure to keep the bladder neither distended nor collapsed.

Aspirated fluid and tissue passes through the aspiration hose 122 to a two-position biopsy valve 172. Ordinarily, the debris will be directed by the valve 172 through a direct hose 174 toward the source of suction. However, when the surgeon sees suspected tissue of which a biopsy would be desirable, the valve 172 can be thrown to direct the debris to a biopsy trap 176. The biopsy trap is a watertight vessel having a transverse screen 178 through which the aspirated debris must pass. The desired tissue can be rapidly collected on the screen and taken away for histological analysis. The biopsy trap should be relatively close to the EUA, for example about 0.3 to 0.5 meter. Because it is close, the hose 122 can clear very rapidly so that the biopsy material can be collected without unnecessary delay after the suspect tissue is spotted. The trap can also be kept sterile so that samples can be collected without contaminating either the sample itself or the surgeon's gloves.

The aspirated debris then passes through a line 179 to the main aspiration trap 180. The trap 180 is a closed vessel having an inlet 182 surrounded by a sock-shaped screen 184, which filters the debris. After filtration, tissue can be removed for **medical (^)** examination in bulk. The trap has an outlet 186 away from the screen 184.

The screens 178 and 184 are not particularly fine. Their openings may advantageously be about 1 mm square so as to pass blood clots, etc., without clogging. On the other hand, the screen gauge is selected to trap pieces of tissue whose size is about the same as the inside diameter of the working tip 80, which is about the dimenson of the tissue that is cored out of the organ being resected.

After filtration, the debris passes through a line 188 to a venting valve 190. The valve 190 has a check valve 192, which opens and passes the pressure on the line 188 to a vacuum switch 194 if the pressure on the line 188 falls to a predetermined low level, which would indicate that the system is clogged. If the vacuum switch 194 opens, a solenoid 196 opens, and this opens a vent line 198, which vents the aspiration pressure to the atmosphere.

Overall control of aspiration pressure is provided by a main valve 200 operated by a solenoid 202.

Pumping is provided by a peristaltic pump 210. Waste aspiration fluid is received in a collecting vessel 220.

FIG. 13 shows elements of an alternate generator for driving the EUA in electro-cauterization of tissue. A double-pole, two-position switch 230 is provided for selecting the source of the signal to be applied to the transducer cable 130. In one position the switch selects the transducer drive signal across capacitors C.sub.1, C.sub.2 in the generator system, as discussed previously with reference to FIGS. 10A and 10B. In the other position the conductor and coaxial shield of the cable 130 are tied together and connected to a radio-frequency source 232. The RF signal is advantageously a pulsed RF current with a peak amplitude of 1500 volts. The waveform is a sharply decaying damped sinusoidal waveform with a frequency of about 500 kHz. The pulse repetition rate is about 20 kHz. To complete the circuit from the RF source to ground, a grounded dispersive electrode 234 is placed in contact with the skin of the patient. The surface area of contact should be as great as possible to prevent burns and shock effects. Thus, RF provided to the tip 80 passes through the patient to ground for endoscopic tissue cauterization.

The generator advantageously has the following operator controls: on/off foot switches for vibration, aspiration, and light; continuous/pulsed **ultrasonic (^)** vibration mode; vibration amplitude; and optionally a switch 230 to connect the EUA to an RF source.

Referring to FIG. 14, the operational end of the open channel endoscopic **ultrasonic (^)** aspirator generally designated 310, comprises a telescope 312 and resonator 314.

Telescope 312 is mounted within a hermetically sealed tube or upper lumen 316. Telescope 312 includes a cylindrical lens system (not shown) and at least one optical fiber (not shown) which transmits light from a light source to the operating site at the end of the telescope. Other illumination sources may be used. The cylindrical lens system allows the surgeon to view the operating site through an eyepiece at a point far removed from the operating site.

Resonator 314 is located within another hermetically sealed tube or lower lumen 318. Resonator 314 is a tube which is cut open from its working end at least to node 332 of aspirator 310. The significance of node 332 is discussed in detail below. Alternatively, resonator 314 may be cut open along its entire length. As a result, the cut portion of resonator 314 is in the form of a channel having a U shape in cross- section.

When the resonator 314 and lower lumen 318 are cut open along their entire length, the telescope 312 is suspended partially within this opening, and an aspirator of minimum size is achieved along its entire length. Casing 320, made of a rigid material, serves principally to maintain the telescope 312 in proper position over the cut portion of resonator 314 and lumen 318.

The opening of the operating tip of the resonator 314 does not affect its **ultrasonic (^)** performance provided that at least half the tip remains. Dissection rates are unaffected since only the lower half of tip contacts tissue in normal usage and the tissue slivers removed by **ultrasonic (^)** dissection using complete tubular tips are never the size of a full bore diameter.

In one embodiment, the resonator 314 is cut only to node 332. Thus, the operating portion of the aspirator is of smaller size than the opposite end which contains lumen 318. As shown in FIGS. 14-18, the tubular casing 20 surrounding the telescope 312 and resonator 314 is not round but is oval in shape to maintain the circumference of the EUA at the preferred minimum range. The oval casing provides accommodation of working implements within the smallest possible perimeter.

Upper lumen 316, in which telescope 312 is housed, fits into the opening at the end of resonator 314. Lower lumen 318, like resonator 314, is a tube which is cut open from its working end at least to node 332 of aspirator 310. Lower lumen 318 is fastened to upper lumen 316 by two beads of adhesive-sealant 326, such as an epoxy, so that upper lumen 316 fits into the opening of lower lumen 318 as shown in detail in

FIG. 176. Upper lumen 16 and lower lumen 318 can be made of any semi-rigid material; however, when upper and lower lumens 316 and 318 are made of an electrically insulating material, upper and lower lumens 316 and 318 electrically isolate resonator 314 from the remainder of the aspirator 310, the patient and the surgeon, so that an electrocauterizing current can be safely applied to the resonator 314.

In order to maintain the tip of resonator 314 adjacent to and in close proximity to upper lumen 316, plug 322 is inserted into lower lumen 318 between the lower surface of resonator 314 and the upper inner surface of lower lumen 318. Plug 322 is crescent shaped in cross-section so that its surfaces engage the lower surface of resonator 314 and the upper inner surface of lower lumen 318, and cause upper lumen 316 to be positioned within the opening of the U shaped tip of resonator 314 as shown in FIGS. 14 and 16. In addition to maintaining the position of the tip of resonator 314 adjacent to upper lumen 316, plug 322 also helps seal the cavity of the aspirator 310 between the lower surface of upper lumen 316 and lower lumen 318, leaving the aspiration channel 328 between resonator 314 and upper lumen 316 as the only opening into that cavity. As shown in FIGS. 22 and 23, a further seal 346 is located at the transformer input section, and this completely prevents the removed material from contacting the remaining parts of the aspirator.

Even without plug 322 in place, however, fluids would enter the channel at the point of tissue dissection. Since there is a very small clearance between the resonator 314 and upper lumen 316, flow is principally restricted to the end of the tip. The hydrodynamic resistance presented to flow below or outside of the channel is greater than the resistance of the open channel and therefore, substantially all flow will take place in the intended manner i.e., by suction through lower lumen 318.

Plug 322 is preferably made of a material that will yield when brought into contact with the ultrasonically vibrating tip of resonator 314. Illustratively, plug 322 is made of an epoxy or polyester resin, a thermoplastic or elastomeric material. By using such yielding materials, any mechanical interference between plug 322 and the ultrasonically vibrating tip of resonator 314 is minimized or removed completely by physical abrasion after the tip of resonator 314 has begun to vibrate. During operation, tissue aspiration proceeds in the same manner as if the tip were a closed tube. Furthermore, since the dissecting edge of the tip appears as a "U" to surgeons viewing this edge through the telescope 312, direct vision of the entire cutting surface is possible. Such a desirable view cannot be obtained using a closed tube aspirator tip.

Use of an electrocauterizing current may prove an advantageous adjunctive procedure in endoscopic **ultrasonic (^)** surgery. In electrocauterization, a metal tip, loop or other **surgical (^)** probe is connected to source of high voltage radio frequency current generated by a spark gap oscillator or a generator that produces the same pulsating flow of electrical current that is characteristic of such oscillators. When the probe is brought into contact with tissue, this current flows through the tissue from the point of contact to a large collecting electrode placed under the patient and in direct contact with the skin.

When the **ultrasonic (^)** tip is effectively insulated from the telescope and sheath, it is possible to not only apply the electrocauterizing potential directly to the tip, but also, if an insulated transducer is employed to vibrate the tip, to simultaneously apply both **ultrasonic (^)** vibration and electrocauterization in an endoscopic instrument for the purpose of dissecting and cauterizing at the same time, and thereby reducing the **surgical (^)** operating time.

Upper lumen 316 and lower lumen 318 are hermetically sealed within semi-rigid tubular casing 320. Due to the shape of upper and lower lumens 316 and 318 and the way in which they are attached to one another, a pair of irrigation fluid channels 324 are formed when upper and lower lumens 316 and 318 are mounted within casing 320, as shown in FIGS. 14 and 16.

As discussed above, resonator 314 has a U shaped cross-section at its operational end, but, according to a preferred embodiment, assumes a closed-off tubular shape at node 332. A cross-sectional drawing of the

aspriator at node 332 is shown in FIG. 17. At node 332 both resonator 314 and lower lumen 318 are tubular in shape and aspiration channel 328 is circular in cross-section. Since resonator 314 does not vibrate at node 332, resonator 314 can contact the inner surface of lower lumen 318 without adversely affecting the vibration of aspriator 314 at its operational end. However, since resonator 314 vibrates throughout its length except at node 332, the remainder of resonator 314 between node 332 and the transducer which causes resonator 314 to vibrate, should not contact the inner surface of lower lumen 18. Therefore, as shown in FIGS. 15 and 18, there is a space 30 between lower lumen 318 and resonator 314 in the aspirator between node 332 and the transducer.

In operation, after the aspirator of the present invention has been partially inserted into a patient's body so that the operational end of the aspriator is positioned adjacent to the tissue that is to be removed by the aspirator, resonator 314 is caused to vibrate at an **ultrasonic (^)** frequency by a transducer. When resonator 314 vibrates at its **ultrasonic (^)** frequency, vibration of the tip of resonator 314 allows the tip to cut through tissue. In order to remove the cut tissue from the patient's body, irrigation fluid is pumped through irrigation fluid channels 324 of the aspirator to the operation site. The irrigation fluid is removed from the operation site by suction that is applied to aspiration channel 328 of resonator 314.

Because the end of resonator 314 near its operational end has a U shape in cross-section, irrigation fluid can enter aspirator channel 324 along the entire cut open section of resonator 314 within lower lumen 318, thereby reducing the amount of suction at any point along the cut open section. However, since the end section of lower lumen 328 is sealed by plug 322, leaving only the U shaped opening of aspiration channel, suction is maintained within lower lumen 318 so that there is sufficient suction at the U-shaped tip of resonator 314.

Although the most preferred resonator shape is a half circle or U shape in cross section, other shapes can be used. For example, a V- shape or an open rectangular or square shape having straight, angled, or rounded corners is also acceptable. The provision of any of these shapes for a channel type (i.e., a base portion with two side portions and an open top) member is within the scope of this invention. Also, plug 322 would be designed to match the configuration of the resonator tip.

When the optimum minimal size of the aspirator is desired, the cut resonator 314 and lower lumen 18 should extend throughout the entire length of the aspirator. This embodiment of the invention is shown in FIGS. 19-24. Since telescope 312 would be located partially within resonator 314 and lower lumen 318, thus providing an arrangement for the instrument which would be similar in cross section to FIG. 16 but extending throughout the entire length of the aspirator. The resonator is anchored at node 332 by seal 340. This seal which can be cast from rubber or other elastomeric material, would also prevent fluids from seeping in the space between resonator 314 and lower lumen 318.

FIGS. 19-24 show the arrangement of telescope 312 and resonator 314 in the area of the transformer input section 342. As shown best in FIG. 20, a groove 344 is cut in the top of the transformer input section 342 to provide space for the telescope 312. The telescope 312 is inserted in groove 344 as shown in FIG. 21. This groove 344 in transformer input section 342 along with the open channel shape of resonator 314 enables telescope 312 to be fitted partially therein so as to minimize the outer diameter or French size of the overall aspiration unit.

In this embodiment, the open channel resonator requires at some point a mechanism for connecting the open channel to a closed tube or passage for removal of biological material and fluid from the aspirator to a waste container, collection vessel, or trap. The transformer input section 342, illustrated in FIGS. 19-23, is bent at a predetermined angle to provide space for the telescope 312. The resonator channel 314 and the telescope 312 also separate at this point. To prevent fluid and biological tissue from flowing back to the telescope 312 or to the handpiece, a castable elastomeric or thermoplastic material is utilized to seal this

area.

FIGS. 23 and 24 illustrate this sealing material 346 and outer sheath 348 for this area of the aspirator. This sealing material 346, generally comprising a elastomeric or thermoplastic self-curing material of relatively low hardness or durometer (i.e., less than 80 Shore A) is essential for preventing the fluid which is desired to be removed through the lower lumen 318 from contaminating or seeping into the handpiece of the aspiration unit. During the manufacture of the aspirator, after the telescope 312 is placed within the resonator channel 314, sheath 348 is placed round the joint area and the synthetic elastomeric or thermoplastic material is cast there between. Preferably, this cast material is a synthetic rubber having a durometer hardness of approximately 40 Shore A. Surprisingly, while high friction losses would be expected for such an arrangement, the losses which are actually encountered are very small, because the actual frequency and vibrational velocities are very low in the encapsulated area. Therefore, isolation of the handpiece of the unit from the fluids removed from the body of the patient is achieved without reducing the vibrational forces that are transmitted to the working tip of the aspirator. The seal 346 also isolates the unit from the atmosphere.

Referring now to FIG. 24, it is evident that seal 340 prevents the fluids which are to be removed from the patient from flowing beneath or outside of resonator 314, such as between resonator 14 and the lower lumen 318. However, this seal 340 does not obviate the need for the cast sealing material 346, since the cast sealing material is used to prevent the fluid, which is in lower lumen 318 from contaminating the handpiece of the overall aspiration unit.

Referring now to FIGS. 25-27, there are illustrated various additional modified working tip arrangements and configurations for the resonator 314 of the invention. As shown in FIG. 27, the working tip can be of a partially blocked off channel which provides advantages with respect to precision cutting of the biological material. This same effect can be achieved by narrowing the channel means by tapering the tip or by reducing the cross sectional area of other configurations, i.e. , such as by gradually diminishing the cross sectional area or size of the channel means or by otherwise configuring the open area of working tip to be of a smaller dimension than of the resonator 314.

In other embodiments, as shown by FIGS. 25 and 27, the tip may comprise part of the tubular unit which is also reduced or restricted in diameter at the working point. The end of the tube can be restricted by means of an overlap 350 or by way of a crimping on the end of the tube to restrict the outer diamter at the working point. This tubular design provides an advantage wherein blockage of the resonator tube 314 is prohibited, since any removed biological material must pass through the smaller bore of the open tip to enter the tube 314. Thus, the material removed would not be able to block or clog the tube 14 when suction is used to withdraw such removed biological material.

While it is apparent that the invention herein disclosed is well calculated to fulfill the objects above stated, it will be appreciated that numerous modifications and embodiments may be devised by those skilled in the art, and it is intended that the appended claims cover all such modifications and embodiments as fall within the true spirit and scope of the present invention.

Drawing Description

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a hypothetical extensional resonator for use in illustrating the background of the invention;

FIG. 2 shows a family of curves illustrating possible stress distributions in the resonator of FIG. 1;

FIG. 3 shows a family of curves illustrating velocity distributions corresponding to the stress distribution curves of FIG. 2;

FIGS. 4A and 4B together form a view, partly broken away, of an endoscopic ultrasonic (^) aspirator (EUA) according to an embodiment of the invention;

FIG. 5A is an elevational view of a resonator assembly including a transducer and first and second velocity transformers for use in the EUA of FIGS. 4A and 4B;

FIG. 5B is a graph showing extension and stress distributions in the components of FIG. 5A;

FIG. 5C shows an alternate resonator assembly;

FIG. 5D shows another alternate resonator assembly;

FIG. 6 is an end view of the EUA taken along line 6--6 in FIG. 4B;

FIG. 7 is a detail of FIG. 6 showing an end view of telescope 28 of the EUA;

FIG. 8 is a plan view of a sealing ring 112 employed in the EUA;

FIG. 9 is an elevational view of part of an alternate embodiment of the invention;

FIGS. 10A and 10B together form a block diagram of an ultrasonic (^) power supply for use with the EUA;

FIG. 11 is a cross-sectional view of the EUA taken along line 11- - 11 of FIG. 4A;

FIG. 12A shows schematically an irrigation system for use with the EUA;

FIG. 12B shows schematically an aspiration system for use with the EUA;

FIG. 13 is a schematic diagram of part of an alternate ultrasonic (^) power supply for use with the EUA.

FIG. 14 is perspective drawing of an embodiment of the open channel endoscopic ultrasonic (^) aspirator of the present invention;

FIG. 15 is a cross-sectional view of the embodiment of FIG. 14 taken along the line 15--15;

FIG. 16 is a cross-sectional view of the embodiment of FIG. 15 taken along the line 16--16;

FIG. 17 is a cross-sectional view of the embodiment of FIG. 15 taken along the line 17--17; and

FIG. 18 is a cross-sectional view of the embodiment of FIG. 15 taken along the line 18--18.

FIG. 19 is a view of the transformer input section of the invention;

FIG. 20 is a view taken along line 20--20 of FIG. 19;

FIG. 21 is a view of the transformer input of the invention when the telescope is inserted;

FIG. 22 is an illustration of the transformer input section with telescope inserted and which is further sealed with an elastomeric material;

FIG. 23 is a view of FIG. 22 with a portion of the elastomeric sealing material removed;

FIG. 24 is a cross sectional view similar to FIG. 15, but illustrating an alternate embodiment of the invention; and

FIGS. 25, 26 and 27 are detailed views of resonator tip modifications for the invention.

Claims

What is claimed is:

1. A method of removing cellular material from a compliant tissue relatively deep within a biological body through a narrow orifice comprising:

providing an elongated surgical (^) instrument which comprises an elongated working end having a length of at least about 8 cm, a circumference of no more than about 29 mm, and a working tip at the forward end thereof, said instrument including means for viewing said working tip and said material to be removed;

inserting said forward end of said elongated surgical (^) instrument into the orifice with said working tip located close to the material to be removed; and

vibrating said working tip longitudinally at a frequency of about 10-20 kHz so as to cavitate the intracellular fluids in such material to destroy the cells thereof while monitoring the removal of said material through the viewing means of said instrument.

2. The method of claim 1, including vibrating said working tip with a longitudinal stroke of at least about 350 microns.

3. The method of claim 2, wherein such longitudinal stroke is at least about 700 microns.

4. The method of claim 1, including vibrating said working tip with a maximum velocity of at least about 1000 cm/sec.

5. The method of claim 4, wherein said maximum velocity is at least about 2000 cm/sec.

6. The method of claim 1, including employing a blunt working tip.

7. The method of claim 1 which further comprises providing the working tip with open channel means to facilitate the removal of said material.

8. The method of claim 7 which further comprises selecting an open channel means which tapers and diminishes along its length.

9. The method of claim 7 which further comprises selecting an open channel means which comprises a base portion and two side portions.

10. The method of claim 7 which further comprises selecting an open channel means which has a cross-sectional area in the shape of a U or V.

11. The method of claim 7 which further comprises selecting an open channel means of substantially uniform cross-section.

12. The method of claim 7 which further comprises selecting an open channel means which further includes tip means of smaller cross- section than the open channel means.

13. The method of claim 1 which further comprises providing said instrument with a radio-frequency source so that said working tip can receive a RF current for cauterization of said tissue when said tip is not vibrating.

14. The method of claim 13 which further comprises providing said instrument with means for selecting the source of signal to be provided to said working tip from one of said radio frequency source or a source for generating **ultrasonic (^)** vibrations.

15. The method of claim 14 which further comprises providing said instrument with a switch as the selecting means.

16. A method of removing cellular material from a compliant tissue at an operating site at least about 8 cm deep within a biological body through a narrow orifice comprising:

providing an elongated **surgical (^)** instrument which comprises an elongated working end having a length of at least about 8 cm, a circumference of no more than about 29 mm, and a working tip at the forward end thereof, said instrument including means for viewing said working tip and said material to be removed;

inserting said elongated **surgical (^)** instrument at least about 8 cm deep into said body through the orifice with said working tip being located close to the material to be removed; and

vibrating said working tip longitudinally at a frequency of about 10-20 kHz so as to produce pressure waves to disintegrate such material while monitoring the removal of said material through the viewing means of said instrument.

17. The method of claim 16 including vibrating said working tip with a longitudinal stroke of at least about 350 microns.

18. The method of claim 17, wherein such longitudinal stroke is at least about 700 microns.

19. The method of claim 16, including vibrating said working tip with a maximum velocity of at least about 1000 cm/sec.

20. The method of claim 19, wherein such maximum velocity is at least about 2000 cm/sec.

21. The method of claim 20, including cavitating the intracellular fluids in such material to destroy the cells thereof.

22. The method of claim 21, including employing a blunt working tip.

23. The method of claim 22, including inserting said narrow elongated **surgical (^)** instrument at least about 19 cm into said body.

24. The method of claim 16 which further comprises providing said instrument with a radio-frequency

source so that said working tip can receive a RF current for cauterization of said tissue when said tip is not vibrating.

25. The method of claim 24 which further comprises providing said instrument with means for selecting the source of signal to be provided to said working tip from one of said radio frequency source or a source for generating **ultrasonic (^)** vibrations.

26. The method of claim 25 which further comprises providing said instrument with a switch as the selecting means.

27. A method of removing cellular material from a compliant tissue at an operating site at least about 8 cm deep within a biological body through an orifice no more than about 29 mm in circumference comprising:

providing a **surgical (^)** instrument having an elongated sheath at least about 8 cm in length and no more than about 29 mm in circumference, the sheath having a hollow bore therethrough,

locating an elongated probe spaced within the hollow bore of the sheath, with a working end of the probe projecting beyond the end of the sheath, the probe having a hollow bore therethrough, thereby forming a first fluid passage in the space between the probe and the sheath, and a second fluid passage within the probe,

inserting the sheath into such body orifice with the working end of the probe being at such operating site and close to such material to be removed,

introducing a fluid into one of the two fluid passages to irrigate such operating site,

vibrating the probe longitudinally at a frequency of about 10-20 kHz so as to produce pressure waves sufficient to disintegrate the cells of such material to be removed, said instrument including means for viewing said working tip and said material to be removed, and

applying suction to the other of the fluid passages to withdraw such fluid and such matter to be removed from such operating sire while monitoring the removal of said material through the viewing means of said instrument.

28. The method of claim 27, including providing a **surgical (^)** instrument no more than about 25 mm in circumference.

29. The method of claim 27, including providing a **surgical (^)** instrument at least about 19 cm in length.

30. The method of claim 29, including providing a **surgical (^)** instrument no more than about 25 mm in circumference.

31. A method for removing cellular material from a compliant tissue within a biological body through a natural or surgically created orifice comprising:

inserting into said orifice an aspirator comprising:

handpiece means; elongated sheath means extending from said handpiece means and having a hollow bore therethrough;

unitary vibration generating means having a first portion which is mounted in said handpiece means, a

second portion which is located in the hollow bore of said sheath, and a third portion comprising a resonator tip which extends beyond the end of said sheath for generating vibrations having an amplitude sufficient to disintegrate said cellular material at a work site in the body of the patient;

means for irrigating said work site with fluid to assist in the removal of disintegrated cellular material;

aspiration means for removing said disintegrated cellular material from said work site; and

means for viewing said work site from said handpiece

so as to position said resonator tip of said aspirator in close proximity to the cellular material to be removed;

vibrating said resonator tip of said aspirator to cavitate the intracellular fluids of the cellular material to destroy the cells thereof; and

removing the destroyed cellular material through said aspiration means of said aspirator.

32. The method of claim 31 which further comprises providing the aspirator with a radio-frequency source so that the resonator tip can receive RF current for cauterizing tissue at the work site when said tip is not vibrating.

33. The method of claim 32 which further comprises providing the aspirator with a switch for selectively connecting one of said radio- frequency source or said vibration generating system to said tip.

34. A method for removing cellular material from a compliant tissue within a biological body through a natural or surgically created orifice comprising:

inserting into said orifice an aspirator comprising:

a hollow handpiece;

an elongated sheath having a hollow bore communicating with the interior of the handpiece and having a working end away from the handpiece;

a vibration source within the handpiece for producing mechanical vibrations in response to an alternating current supplied to said vibration source;

means for supplying such alternating current to said vibration source;

elongated tool means coupled to the vibration source and passing through said hollow bore of the sheath to a work site beyond the working end of the sheath for transmitting such mechanical vibrations to the work site, said tool means including working tip means for contact with the work site;

viewing means extending from the handpiece to the work site for providing a view from the handpiece of the work site;

means for supplying fluid to said work site through a fluid space defined between said tool means and said hollow bore of said sheath;

fluid detection means for detecting the presence of fluid in the fluid space and connected to the means for

supplying alternating current for terminating such supplied alternating current and thereby stopping such mechanical vibrations when such fluid is not present, and

means for removing said fluid from said work site through conduit means, the end of said conduit means nearest the work site formed by said working tip means

so as to position said working tip means of said aspirator in close proximity to the cellular material to be removed;

vibrating said working tip means of said aspirator to cavitate the intracellular fluids of the cellular material to destroy the cells thereof; and

removing the destroyed cellular material through said fluid removal means of said aspirator.

35. The method of claim 34 which further comprises providing the aspirator with a radio-frequency source so that the elongated tool means can receive RF current for cauterizing tissue at the work site when said tool means is not vibrating.

36. The method of claim 35 which further comprises providing the aspirator with a switch for selectively connecting one of said radio- frequency source or said vibration generating system to said elongated tool means.

37. A method for removing cellular material from a compliant tissue within a biological body through a natural or surgically created orifice comprising:

inserting into said orifice an apparatus comprising:

a handpiece;

an elongated sheath extending from the handpiece and having a hollow bore therethrough;

high frequency vibration source means mounted in the handpiece for generating a first amplitude;

first velocity transformer means located in the hollow bore within the sheath and spaced therefrom, having an input end and an output end, the input end being coupled to the vibration source to be vibrated thereby, and the output end vibrating in response to such received vibrations with a second amplitude greater than such first amplitude;

second velocity transformer means having an input end and an output end, the input end being coupled to the output end of the first transformer to be vibrated thereby, and the output end vibrating in response to such received vibrations with a third amplitude greater than such second amplitude, said third amplitude being sufficient to disintegrate said cellular material, said second velocity transformer means having working tip means extending beyond the end of the sheath away from the handpiece for contacting said cellular material, said working tip means having a smaller cross-sectional area than that of said second velocity transformer means;

the second transformer means when vibrating, having a substantially constant mechanical stress level in substantially all of its length, the output end of the first transformer velocity means and the second velocity transformer means forming a unitary component to minimize the production of transverse flexural vibrations;

said high-frequency vibration source means and said first and second velocity transformer means being elongated and having a continuous hollow bore extending along a common longitudinal axis thereof, thereby forming first fluid passage means in a space defined between the first and second velocity transformer means and the sheath, and second fluid passage means along said common longitudinal axis;

means for introducing fluid into one of said fluid passage means to irrigate an operating site adjacent said working tip means of the second velocity transformer means where said cellular material is contacted and disintegrated; and

means for applying suction to the other of said fluid passage means to remove such fluid and such disintegrated cellular material from such operating site

so as to position said working tip means of said apparatus in close proximity to the cellular material to be removed;

vibrating said working tip means of said apparatus to cavitate the intracellular fluids of the cellular material to destroy the cells thereof; and

removing the destroyed cellular material through said other fluid passage of said apparatus.

38. The method of claim 34 which further comprises providing the aspirator with a radio-frequency source so that the working tip means can receive RF current for cauterizing tissue at the work site when said tip is not vibrating.

39. The method of claim 38 which further comprises providing the aspirator with a switch for selectively connecting one of said radio- frequency source or said vibration generating system to said working tip means.

40. A method for removing cellular material from a compliant tissue within a biological body through a natural or surgically created orifice comprising:

inserting into said orifice an aspirator comprising:

a hollow handpiece;

an elongated sheath having a hollow bore communicating with the interior of the handpiece and having a working end away from the handpiece;

a vibration source within the handpiece for producing mechanical vibrations in response to an alternating current supplied to said vibration source;

means for supplying such alternating current to said vibration source;

elongated tool means coupled to the vibration source and passing through a hollow bore of the sheath to a work site beyond the working end of the sheath for transmitting such mechanical vibrations to such work site;

viewing means extending from the handpiece to such work site for providing a view from the handpiece of such work site;

means for supplying fluid to a fluid space defined between said tool means and said hollow bore of said

sheath; and

fluid detection means for detecting the presence of fluid in the fluid space and connected to the means for supplying alternating current for terminating such supplied alternating current and thereby stopping such mechanical vibrations when such fluid is not present

so as to position said elongated tool means of said apparatus in close proximity to the cellular material to be removed;

vibrating said elongated tool means of said aspirator to cavitate the intracellular fluids of the cellular material to destroy the cells thereof; and

removing the destroyed cellular material.

41. The method of claim 40 which further comprises providing the aspirator with a radio-frequency source so that the elongated tool means can receive RF current for cauterizing tissue at the work site when said tool means is not vibrating.

42. The method of claim 41 which further comprises providing the aspirator with a switch for selectively connecting one of said radio- frequency source or said vibration generating system to said tool means.

43. A method for removing cellular material from a compliant tissue within a biological body through a natural or surgically created orifice comprising:

inserting into said orifice an apparatus comprising:

a handpiece;

an elongated sheath extending from the handpiece and having a hollow bore therethrough;

vibration means comprising:

high-frequency vibration source means mounted in the handpiece for vibrating with a selected wavelength and with a first amplitude;

first velocity transformer means located in the hollow bore within the sheath and spaced therefrom for amplifying vibrations from the vibration source means and having an input section and an output section, the input section being unitary with the vibration source means and the output section being smaller in cross-sectional area than the input section, and

second velocity transformer means having an input end and an output end, the input end being unitary with the output section of the first velocity transformer means for amplifying vibrations thereof to a sufficient velocity to disintegrate said cellular material and to minimize the production of transverse flexural vibrations, the output end vibrating in response to such received vibrational energy for further transmitting such vibrational energy;

said second velocity transformer means having a working tip extending beyond the end of the sheath away from the handpiece;

said high-frequency vibration source means and each of said velocity transformer means being elongated and each having a continuous hollow bore extending along a common longitudinal axis thereof, thereby

forming; first fluid passage means in a space defined between the first and second velocity transformer means and the sheath, and second fluid passage means along said common longitudinal axis;

means for introducing fluid into one of said fluid passage means to irrigate an operating site adjacent the working tip of the second velocity transformer means where said cellular material is disintegrated, and

means for applying suction to the other of said fluid passage means to remove said fluid and disintegrated cellular material from such operating site

so as to position said working tip of said apparatus in close proximity to the cellular material to be removed;

vibrating said working tip of said apparatus to cavitate the intracellular fluids of the cellular material to destroy the cells thereof; and

removing the destroyed cellular material.

44. The method of claim 43 which further comprises providing the aspirator with a radio-frequency source so that the working tip can receive RF current for cauterizing tissue at the work site when said tip is not vibrating.

45. The method of claim 44 which further comprises providing the aspirator with a switch for selectively connecting one of said radio- frequency source or said vibration generating system to said tip.

46. A method for removing cellular material from a compliant tissue within a biological body through a natural or surgically created orifice comprising:

inserting into said orifice an aspirator comprising:

a hollow handpiece;

an elongated sheath having a hollow bore communicating with the interior of the handpiece and having a working end away from the handpiece;

high-frequency vibration source means mounted in the handpiece comprising transducer means for generating high-frequency vibrations of a selected wavelength and having a first amplitude and vibration amplifying means for receiving the vibrations generated by the transducer means and amplifying said vibrations to **ultrasonic (^)** vibrations of a frequency of between 10 and 20 KHz, said vibration amplifying means comprising:

first velocity transformer mens of an elongated member having an input end and an output end for amplifying vibrations from said vibration source means the input end being coupled to the transducer means and the output end vibrating in response to such received vibrations with a second amplitude greater than said first amplitude, and

second velocity transformer means of an elongated member having an input end and an output end for amplifying vibrations from the first velocity transformer means, the input end being unitary with the output end of the first velocity transformer means to be vibrated thereby and to minimize the production of transverse flexural vibrations, the output end vibrating in response to such received vibrations with the desired frequency while further having a substantially constant mechanical stress level in substantially all its length;

elongated tool means coupled to the output end of said second velocity transformer means and passing through the hollow bore of the sheath to a work site beyond the working end of the sheath for transmitting the amplified vibrations to said work site for disintegration of said cellular material thereof;

means for aspirating said disintegrated cellular material portion from the work site; and

viewing means extending from said handpiece to said work site for providing a view from the handpiece of said work site

so as to position said elongated tool means of said aspirator in close proximity to the cellular material to be removed;

vibrating said elongated tool means of said aspirator to cavitate the intracellular fluids of the cellular material to destroy the cells thereof; and

removing the destroyed cellular material.

47. The method of claim 46 which further comprises providing the aspirator with a radio-frequency source so that the elongated tool means can receive RF current for cauterizing tissue at the work site when said tool means is not vibrating.

48. The method of claim 47 which further comprises providing the aspirator with a switch for selectively connecting one of said radio- frequency source or said vibration generating system to said tool means.

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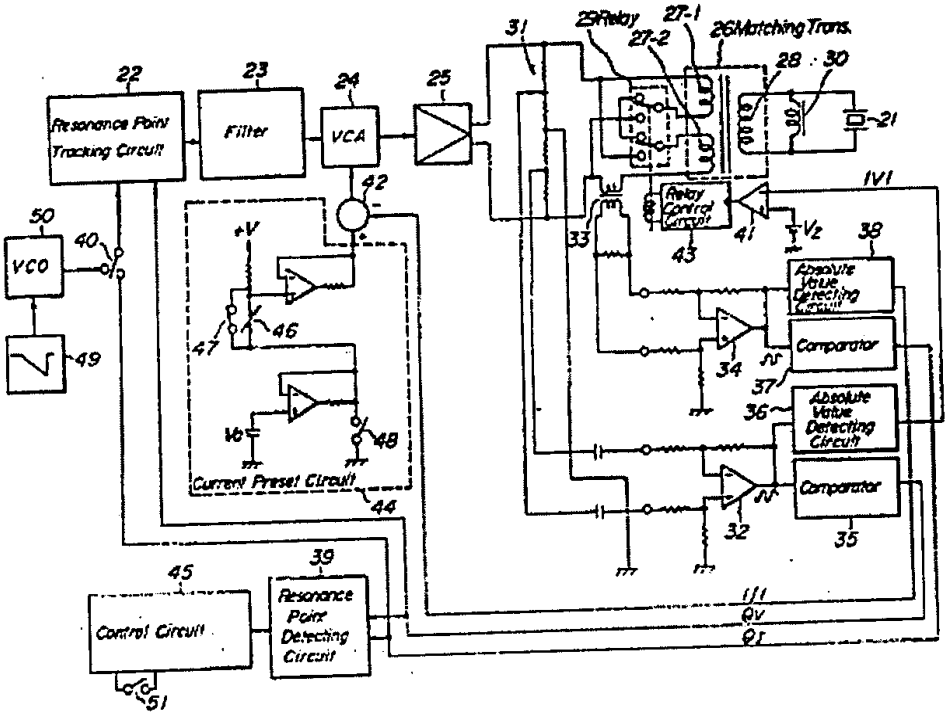
Search scope: US EP WO JP; Full patent spec.
Years: 1990-2001
Text: "Ultrasonic" and "medical" and "filter" and "surgical"



US5151085

Apparatus for generating ultrasonic (^) oscillation

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Application No. 513230, **Filed** 19900423, **Issued** 19920929

Abstract: The apparatus includes an ultrasonic (^) transducer having a hand piece, an ultrasonic (^) vibrating element secured to the hand piece and a probe coupled with the hand piece for propagating the ultrasonic (^) oscillation produced by the ultrasonic (^) vibrating element, a driving circuit for producing a driving signal for the ultrasonic (^) vibrating element, a voltage controlled amplifier for amplifying the driving signal, an impedance matching transformer having a plurality of primary windings connected to the output of the voltage controlled amplifier via a switching circuit and a secondary winding connected to the ultrasonic (^) vibrating element, a probe identification circuit for detecting the probe connected to the hand piece to produce a probe identification signal, a feedback control loop for generating a control voltage which is applied to the voltage controlled amplifier for controlling the amplification factor thereof in accordance with a driving current of the driving signal, an impedance detecting circuit for detecting the

impedance of the ultrasonic (^) transducer and controlling the switching circuit such that a given primary winding is connected to attain the impedance matching between the driving circuit and the ultrasonic (^) transducer, and a voltage limiter arranged in the feedback control loop such that the maximum value of the control voltage is limited in accordance with the probe identification signal.

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US Patents Cited: 3746897 4181864 4583529 4703213 4966131 4970656 4973876 5026387 5042460

Foreign References: JP63162086 JP63212341 JP63212342

Agent(s): Stevens, Davis, Miller & Mosher

Examiner(s): Cohen, Lee S.; Pfaffle, K. M.

Go to Claims

Background and Summary

BACKGROUND OF THE INVENTION

Field of the Invention and Related Art Statement

The present invention relates to an apparatus for generating an ultrasonic (^) oscillation, and more particularly to an apparatus for generating an ultrasonic (^) oscillation comprising an ultrasonic (^) transducer having an ultrasonic (^) vibrating element for producing an ultrasonic (^) oscillation and a probe for transmitting the oscillation produced by the ultrasonic (^) vibrating element, and a driving circuit for supplying a driving signal to the ultrasonic (^) vibrating element.

Heretofore, there have been proposed various kinds of apparatuses using the ultrasonic (^) transducer. For instance, ultrasonic surgical (^) knives and ultrasonic (^) working machines have been developed. In these ultrasonic (^) apparatuses, it is advantageous to effect the impedance matching between the ultrasonic (^) transducer and the driving circuit in order to improve the driving efficiency of the ultrasonic (^) vibrating element.

FIGS. 1A and 1B show the known ultrasonic (^) probe in which vibrating rods 2 and 3 having different lengths are detachably secured to an ultrasonic (^) transducer 1. The inventor of the instant application has experimentally confirmed that the impedance of the probe illustrated in FIG. 1B is smaller than that of the probe depicted in FIG. 1A by about five times. Therefore, when these probes are driven by the same driving circuit, if the output impedance of the driving circuit is fixedly matched to either one of the vibrating rods 2 and 3, the impedance matching could not be attained for the other of the vibrating rods 3 or 2 and the driving efficiency of the ultrasonic (^) vibrating element 1 would be decreased to a great extent.

In order to mitigate the above mentioned drawback, in a Japanese Patent Laid-open Publication Kokai Sho 63-162086, there has been proposed an ultrasonic (^) transducer in which taps on a secondary side of a

coupling transformer for electromagnetically coupling the ultrasonic (^) vibrating element and the driving circuit are switched in accordance with the amplitude of the oscillation or vibration of the ultrasonic (^) vibrating element.

However, in the ultrasonic (^) oscillation generating apparatus disclosed in said Japanese Patent Laid-open Publication Kokai Sho 63- 162086, there is a problem that the impedance matching could be no more attained due to the fact that the adjustment of the impedance matching is carried out on the basis of the amplitude of the oscillation. That is to say, in the ultrasonic (^) transducer the amplitude of the oscillation is proportional to an amplitude of a current passing through the ultrasonic (^) vibrating element, so that if the impedance of the transducer circuit is increased twice, the taps on the secondary side of the coupling transformer are changed such that the voltage applied to the ultrasonic (^) vibrating element is increased also twice in order to keep the amplitude of the current unchanged. Then, the impedance of the transducer circuit viewed from the primary side of the transformer is decreased by four times, because the ratio of the primary winding to the secondary winding becomes 1:2. This results in that the impedance of the load for the driving circuit is decreased by two times, although the impedance of the transducer circuit is increased by two times. Therefore, the impedance matching could not be attained and the ultrasonic (^) vibrating element could not be driven efficiently.

Further, in the known ultrasonic (^) generating apparatus, the taps are provided on the secondary side of the coupling transformer, i.e. on the vibrating element side of the transformer. When the apparatus is applied to the ultrasonic surgical (^) knife, a switching circuit for switching the secondary winding portions is arranged in the circuitry on the patient side, so that the electrical insulation should be effected to a very high degree in order to achieve protection against the electric leakage and discharge. This apparently increases the cost of the apparatus.

In order to attain a proper impedance matching, it would be also considered that the impedance of ultrasonic (^) transducers to be used are previously measured and when an ultrasonic (^) transducer is used, the impedance matching is attained manually in accordance with the measured impedance of the relevant transducer. In such a solution, there might be produced another problem of the misoperation of the user and the driving circuit might be broken under the overload condition.

In Japanese Patent Laid-open Publication Kokai Sho 63-212341 and 63-212342, there are described further known ultrasonic (^) apparatuses in which objects such as hematoma and tumor produced within a patient body are broken into pieces by irradiating the ultrasonic (^) beam thereupon by inserting the ultrasonic (^) endoscope and pieces of the objects are sucked out of the body via a tube arranged in the endoscope. In such ultrasonic surgical (^) operating apparatus, it is desired that the amplitude of the ultrasonic (^) probe driven by the ultrasonic (^) vibrating element is kept constant regardless of the acoustic impedance of the objects. As explained above, since the amplitude of the ultrasonic (^) vibrating element is proportional to the amplitude of the current passing through the element, the output of the oscillator in the driving circuit is supplied to the vibrating element via a voltage controlled amplifier (VCA) whose amplification factor can be changed by a control voltage, and the amplification factor of the VCA is adjusted in accordance with the driving current such that the driving current can be kept constant.

In the above mentioned ultrasonic (^) apparatus in which the ultrasonic (^) vibrating element is driven by the constant current circuit, the construction of the apparatus can be made simple and the amplitude of the ultrasonic (^) oscillation can be maintained substantially constant. However, the electric stability of the known apparatus sometimes becomes deteriorated. For example, in the above explained ultrasonic surgical (^) apparatus, when the tip of the ultrasonic (^) probe is urged against the object, the electric property of the probe is changed to a large extent in accordance with the objects and the amplitude of the driving current becomes extremely small. Then, the constant current circuit operates such that the control voltage for the VCA is abnormally increased and the voltage applied to the ultrasonic (^) vibrating

element becomes larger than threshold voltages of the element and driving circuit, so that they might be broken. This is quite dangerous for the patient.

SUMMARY OF THE INVENTION

The present invention has for its object to provide a novel and useful apparatus for generating the ultrasonic (^) oscillation in which the above mentioned drawbacks of the known apparatuses can be removed and the impedance matching between the ultrasonic (^) vibrating element and the driving circuit can be always attained correctly in an automatic manner and the ultrasonic (^) vibrating element can be driven always efficiently.

It is another object of the present invention to provide an apparatus for generating the ultrasonic (^) oscillation in which the ultrasonic (^) vibrating element can be always driven stably without damaging the driving circuit and element as well as without damaging or injuring the patient.

According to the invention, an apparatus for generating an ultrasonic (^) oscillation comprises:

an ultrasonic (^) transducer having an ultrasonic (^) vibrating element for producing an ultrasonic (^) oscillation and a probe for transmitting the ultrasonic (^) oscillation produced by the ultrasonic (^) vibrating element;

a driving circuit for supplying a driving signal to said ultrasonic (^) vibrating element:

an impedance matching means connected between said ultrasonic (^) transducer and said driving circuit for matching the output impedance of the driving circuit to the impedance of said ultrasonic (^) transducer;

an impedance detecting means for detecting the impedance of said ultrasonic (^) transducer to generate an impedance detecting signal; and

controlling means for automatically controlling said impedance matching means in accordance with said impedance detection signal supplied from said impedance detecting means such that the output impedance of said driving circuit is matched to the impedance of said ultrasonic (^) transducer.

In a preferred embodiment of the apparatus according to the invention, said impedance matching means comprises a matching transformer having a plurality of primary windings and a secondary winding connected to the ultrasonic (^) transducer, a switching circuit for selectively connecting one of said primary windings to the driving circuit, and a control circuit for controlling said switching circuit in accordance with said impedance detection signal supplied from said impedance detecting means such that the output impedance of said driving circuit is matched with the impedance of the ultrasonic (^) transducer.

According to further aspect of the invention, an apparatus for generating an ultrasonic (^) oscillation comprises:

an ultrasonic (^) transducer having an ultrasonic (^) vibrating element for producing an ultrasonic (^) oscillation and a probe for transmitting the ultrasonic (^) oscillation produced by the ultrasonic (^) vibrating element;

a driving circuit for supplying a driving signal to said ultrasonic (^) vibrating element;

an impedance matching means connected between said **ultrasonic (^)** transducer and said driving circuit for matching the output impedance of the driving circuit to the impedance of said **ultrasonic (^)** transducer;

a probe identifying means for identifying a kind of said **ultrasonic (^)** transducer to generate a probe identification signal; and

controlling means for automatically controlling said impedance matching means in accordance with said probe identification signal supplied from said probe identifying means such that the output impedance of said driving circuit is matched to the impedance of said **ultrasonic (^)** transducer.

According to another aspect of the invention, an apparatus for generating an **ultrasonic (^)** oscillation comprises:

an **ultrasonic (^)** transducer having an **ultrasonic (^)** vibrating element for producing an **ultrasonic (^)** oscillation and a probe for transmitting the oscillation produced by the **ultrasonic (^)** vibrating element:

a driving circuit having a voltage controlled amplifier for supplying a driving power to said **ultrasonic (^)** vibrating element;

a feedback loop connected between said **ultrasonic (^)** transducer and said driving circuit for detecting a current of said driving power supplied to said **ultrasonic (^)** transducer and applying a control voltage corresponding to said current of the driving power to said voltage controlled amplifier to control an amplification factor of the voltage controlled amplifier; and

a voltage limiting means connected in said feedback loop for limiting an amplitude of said control voltage.

According to still another aspect of the invention, an apparatus for generating an **ultrasonic (^)** oscillation comprises:

an **ultrasonic (^)** transducer having an **ultrasonic (^)** vibrating element for producing an **ultrasonic (^)** oscillation and a probe for transmitting the **ultrasonic (^)** oscillation produced by the **ultrasonic (^)** vibrating element;

a driving circuit having a voltage controlled amplifier for supplying a driving power to said **ultrasonic (^)** vibrating element;

a feedback loop connected between said **ultrasonic (^)** transducer and said driving circuit for detecting a current of said driving power supplied to said **ultrasonic (^)** transducer and applying a control voltage corresponding to said current of the driving power to said voltage controlled amplifier to control an amplification factor of the voltage controlled amplifier;

voltage limiting means having a plurality of voltage limiting elements connected in said feedback loop for limiting an amplitude of said control voltage;

probe identifying means for identifying a kind of said **ultrasonic (^)** transducer to generate a probe identification signal; and

controlling means for automatically switching said plurality of voltage limiting elements of the voltage limiting means in accordance with the probe identification signal produced by the probe identifying means.

Detailed Description

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Embodiments

FIG. 2 shows the principal construction of the apparatus for generating the ultrasonic (^) oscillation according to the invention. An output signal generated from a driving circuit 11 is supplied via a matching transformer 12 which serves as a variable matching means for an ultrasonic (^) transducer or probe 13 including ultrasonic (^) vibrating element 13a and vibrating rod 13b. The matching transformer 12 comprises taps 14- 1 and 14-2 provided on the primary side of the transformer for changing the number of winding turns. To the primary side of the transformer 12 is connected an impedance detection circuit 15 for detecting the impedance of the ultrasonic (^) transducer 13 detected by the impedance detection circuit 15, a controlling means comprising a preset circuit 16 and a relay 17 is driven such that the output impedance of the driving circuit 11 is changed by changing the taps 14-1 and 14-2 to attain the optimum condition for the ultrasonic (^) transducer 13. In this manner, the matching between the driving circuit 11 and the ultrasonic (^) transducer 13 can be attained in an automatic manner, so that the ultrasonic (^) vibrating element 13a can be always driven efficiently.

By constructing the apparatus in the manner explained above, the impedance of the ultrasonic (^) transducer 13 can be always correctly matched to the impedance of the driving circuit 11 in an automatic manner, so that the ultrasonic (^) transducer can be driven in a very efficient manner.

FIG. 3 is a block diagram showing a first embodiment of the ultrasonic (^) oscillation generating apparatus according to the invention. In the present embodiment, voltage phase and current phase of a driving signal for the ultrasonic (^) transducer comprising an ultrasonic (^) vibrating element 21 are detected, and the frequency of the driving signal is automatically controlled to be equal to a resonance frequency of the ultrasonic (^) vibrating element by a resonance point tracking circuit 22 in accordance with the detected voltage and current phases. That is to say, the so-called phase lock loop control is effected.

An output signal from the resonance point tracking circuit 22 is supplied to a filter (^) 23 and is converted into a driving signal having a sinusoidal waveform. Then, the driving signal is supplied via a voltage controlled amplifier (VCA) 24 whose amplification factor can be controlled and a power amplifier 25 to a primary side of a matching transformer 26. The matching transformer 26 includes two primary windings 27-1 and 27-2 and a secondary winding 28. The two primary windings 27-1 and 27-2 may be connected in series or in parallel with each other by means of a relay 29. To the secondary winding 28 are connected the ultrasonic (^) vibrating element 21 and a compensating inductor 30 for canceling the damping capacitance of the element 21. It should be noted that in the present embodiment the ratio of turns of the windings 27-1, 27-2 and 28 is set to 1:1:2 so that the ratio of the primary and secondary windings may be changed between 1:1 and 1:2.

The voltage applied to the ultrasonic (^) vibrating element 21 via the power amplifier 25 is detected by a potentiometer 31 connected in parallel with the primary side of the matching transformer 26, and an output of the potentiometer 31 is applied to a differential amplifier 32 to remove in-phase noise contained therein. The current passing through the ultrasonic (^) vibrating element 21 is detected by a current sensor 33 connected in series with the primary side of the matching transformer 26 and the detected signal is supplied to a differential amplifier 34 to remove in-phase noise contained therein.

The voltage detection signal generated by the differential amplifier 32 is supplied to a comparator 35 to

detect a voltage phase signal .theta..sub.V and is also supplied to an absolute value detecting circuit 36 to derive an absolute value of the detected voltage .vertline. V.vertline.. Similarly, the current detection signal generated from the differential amplifier 34 is supplied to a comparator 37 to produce a current phase signal .theta..sub.1 and is supplied to an absolute value detecting circuit 38 to derive an absolute value of the detected current .vertline.I.vertline..

The voltage phase signal .theta..sub.V produced from the comparator 35 is supplied to a resonance point tracking circuit 22 as well as to a resonance point detecting circuit 39 for detecting the resonance point by sweeping the frequency of the driving signal, which will be explained later. The current phase signal .theta..sub.1 produced by the comparator 37 is supplied to the resonance point detecting circuit 39 as well as to the resonance point tracking circuit 22 via a switch 40. The absolute value .vertline.V.vertline. of the voltage detection signal generated by the absolute value detecting circuit 36 is supplied to one input of a voltage comparator 41 and the absolute value . vertline.I.vertline. of the current detection signal generated by the absolute value detecting circuit 38 is supplied to one input of a differential amplifier 42. To the other input of the differential amplifier 41 is applied a predetermined preset voltage V.sub.Z and a difference between the absolute value .vertline.V.vertline. and the preset value V.sub.Z is latched by a relay control circuit 43 to control the relay 29. To the other input of the differential amplifier 42 is applied a preset current signal from a current preset circuit 44 to detect a difference between the absolute value .vertline.I.vertline. of the current detection signal and the preset current value. The amplification factor of the VCA 24 is controlled by the output signal of the differential amplifier 42 such that the difference becomes zero, so that the **ultrasonic (^)** vibrating element 21 can be driven with the constant current corresponding to the preset current value. It should be noted that the output of the resonance point detecting circuit 39 is supplied to a control circuit 45.

The current preset circuit 44 comprises means for generating a reference voltage V.sub.o for presetting the low constant current during the start time period, a variable resistor 46 for presetting a constant current for driving the **ultrasonic (^)** vibrating element 21 at a predetermined amplitude in the resonance point tracking mode, a switch 47 for connecting or disconnecting the variable resistor 46, and a switch 48 for forcedly stopping the vibration of the **ultrasonic (^)** vibrating element 21 by making the control voltage applied to VCA 24 zero.

In order to sweep the frequency of the driving signal for the **ultrasonic (^)** vibrating element 21, there is provided a generator 49 for generating the sawtooth signal and the sawtooth signal is supplied to a voltage controlled oscillator (VCO) 50 to generate a reference sweep signal having a linearly varying frequency. The reference sweep signal thus produced is supplied to the resonance point tracking circuit 22 via the switch 40. It should be noted that the switch 40, relay control circuit 43, switches 47, 48, generator 49 and other circuits are controlled by the control circuit 45. Further, to the control circuit 45 is connected a switch 51 for actuating and stopping the apparatus.

Now the operation of the apparatus of this embodiment will be explained also with reference to a flow chart shown in FIG. 4.

While the switch 51 is made off, the switch 40 is connected to VCO 50, and switches 47 and 48 are made on and off, respectively. Moreover the winding ratio of the primary and secondary sides of the matching transformer 26 is set to 1:1. When the switch 51 is made on, the **ultrasonic (^)** vibrating element 21 is driven at the low constant current set by the reference voltage V.sub.o of the current preset circuit 44, and further the generator 49 is actuated to control VCO 50 and the frequency of the driving signal is swept in accordance with the reference sweep signal generated from VCO 50. That is to say, the resonance point tracking circuit 22 is locked to the output from VCO 50 and the oscillation frequency of the PLL is scanned by scanning the output frequency of VCO 50 in accordance with the output of the generator 49.

During the above mentioned frequency scan, the **ultrasonic (^)** vibrating element 21 is driven at the constant current mode owing to the operation of the current preset circuit 44, differential amplitude 42 and VCA 24. Therefore, if the constant current is set to .vertline.I.sub. o .vertline., the impedance .vertline.Z.vertline. can be detected by monitoring the voltage .vertline.V.vertline. from the following equation: ##EQU1## The impedance .vertline.Z.vertline. becomes minimum at the resonance point f.sub.r during the frequency sweep, so that the voltage .vertline.V.vertline. also becomes minimum at the resonance point f.sub.r as shown in FIGS. 5A and 5B which correspond to the . vertline.V.vertline. property of the **ultrasonic (^)** transducer illustrated in FIGS. 1A and 1B. Therefore, by comparing .vertline.V.vertline. with the preset voltage V.sub.Z in the comparator 41, it can be detected that the **ultrasonic (^)** transducer having the small impedance is connected when the comparator 41 generates the output signal during the scan, and the **ultrasonic (^)** transducer having the large impedance is connected when the comparator 41 does not generate the output signal.

When it is detected that the impedance .vertline.Z.vertline. of the **ultrasonic (^)** transducer is large, the switch 48 is made on to set the control voltage for VCA 24 to zero to stop the output of the power amplifier 25. In this condition, the relay 29 is actuated in accordance with the impedance detection result latched in the relay control circuit 43 and the ratio of the windings of the matching transformer 26 is changed to 1:2. In this manner, the output impedance of the driving circuit is matched to the impedance of the **ultrasonic (^)** transducer connected to the driving circuit. After that, the switch 48 is made off and the generator 49 is actuated again to scan the driving frequency for the **ultrasonic (^)** vibrating element 21 in accordance with the reference sweep signal, and the resonance point is detected by the resonance point detection circuit 39 in accordance with the voltage phase signal .theta.. sub.V and current phase signal .theta..sub.1. At the resonance point, the phase difference between these phase signals becomes zero.

After the resonance point has been detected, the switch 40 is connected to the comparator 37 to lock the resonance point tracking operation. When the tracking is locked, the switch 47 is made off and the **ultrasonic (^)** vibrating element 21 is driven at the current value set by the variable resistor 46.

When it is detected that the **ultrasonic (^)** transducer has the small impedance .vertline.Z.vertline. and the winding ratio of the matching transformer 26 may be remained 1:1, the resonance point is detected during this frequency scan, so that the rescan is not effected and the switch 40 is connected to the comparator 37 after the resonance point has been detected to enter into the lock in mode.

As explained above, in the present embodiment, the dynamic impedance of the **ultrasonic (^)** vibrating element 21 is detected to automatically correct the impedance matching, and thus the error in the manual matching can be effectively avoided and the **ultrasonic (^)** transducer can be driven always efficiently even if the impedance of the probe connected to the **ultrasonic (^)** vibrating element is changed to a great extent. In this manner, the **ultrasonic (^)** apparatus such as the **ultrasonic surgical (^)** knife and **ultrasonic (^)** working machine can be driven efficiently. Further the impedance matching is effected by changing the taps on the primary side of the matching transformer, so that when the apparatus is applied to the **medical (^)** devices such as the **ultrasonic surgical (^)** knife, it is not necessary to include the switching circuits and control circuits in the circuit on the patient side and the patient can be protected against the danger such as the breakage of insulation and leakage.

FIGS. 6A and 6B are is a block diagram showing an embodiment of the **ultrasonic surgical (^)** knife to which the **ultrasonic (^)** oscillation generating apparatus according to the invention is applied. In the present embodiment, a hand piece 55 comprises an **ultrasonic (^)** vibrating element 56 of Langevin type to which a short probe 57 and a long probe 58 having different impedance may be detachably secured. The **ultrasonic (^)** vibrating element 56 is connected to a secondary side of a matching transformer 59 and is driven by the output of a phase lock loop (PLL) 60. The matching transformer 59 comprises two primary windings 61-1 and 61- 2 and a secondary winding 62. In a similar manner to the embodiment shown in

FIG. 2, the ratio of turns between the primary and secondary windings can be changed by a select circuit 63 including a relay and control circuit. Across the vibrating element 56 is connected an inductor 64 for canceling the damping capacitance of the element.

The phase lock loop 60 comprises a phase comparator (PC) 65, a charge pump 66 for converting the digital output of the phase comparator into the analog signal, a loop **filter (^)** 67 and a voltage controlled oscillator (VCO) 68. The output of the charge pump 66 is applied to VCO 68 as the control voltage via the loop **filter (^)** 67. The output of VCO 68 is supplied to the **filter (^)** 69 as well as to a frequency divider 70, and the output of the frequency divider 70 is supplied to the **filter (^)** 69, so that the rectangular output signal from VCO 69 is converted into a sinusoidal driving signal which contains only the resonance component of the **ultrasonic (^)** vibrating element 56 to avoid unnecessary heat radiation from the element. In the present embodiment, the **filter (^)** 69 is formed by a switched capacitor **filter (^)** (SCF) whose cut-off frequency can be changed by an external clock input. When the **filter (^)** is composed of such SCF, the amplitude variation and the phase rotation of the output signal of the **filter (^)** can be removed, and therefore the constant current control and PLL are hardly affected by these variations so that the rectangular- sinusoidal conversion can be carried out in an ideal manner. Moreover, the impedance of the **ultrasonic (^)** vibrating element 56 can be detected precisely during the frequency sweep of the driving signal, because only the fundamental wave is used.

The output of the **filter (^)** 69 is supplied via voltage controlled amplifier (VCA) 71, buffer amplifier 72, switch circuit 73 and power amplifier 74 to the primary side of a matching transformer 59. By means of the matching transformer 59, it is possible to electrically isolate the circuit of the **ultrasonic (^)** vibrating element 56 from the driving circuit and to attain the impedance matching between the power amplifier 74 and the **ultrasonic (^)** vibrating element 56.

The voltage applied to the **ultrasonic (^)** vibrating element 56 and the current flowing through the element are detected by a voltage and current detecting circuit 75 which includes voltage detecting potentiometer and current sensor which are similar to those shown in FIG. 2. The obtained voltage and current detection signals are supplied to differential amplifiers 76 and 77, respectively. In this manner the problem of in-phase noise which is inherent to the detection of the high voltage and large current can be effectively removed by means of the differential amplifiers 76 and 77. Furthermore, although the positive and negative terminals of the power amplifier 74 are connected inversely or the power amplifier is not a type whose one output terminal is not connected to the ground, the voltage and current detection signals can be obtained stably.

The voltage detection signal V generated from the differential amplifier 76 is supplied to a comparator 7i to detect a voltage phase detection signal .theta..sub.V as well as to an absolute value detecting circuit 79 to detect an absolute value of the amplitude of the detected voltage .vertline.V.vertline.. Similarly the current detection signal T produced by the differential amplifier 77 is supplied to as comparator 80 to derive a current phase detection signal .theta..sub.1 as well as to the solute value detecting circuit 81 to detect an absolute value of the detected current .vertline.I.vertline..

The voltage phase signal .theta..sub.V derived from the comparator 78 is supplied to a phase comparator 82 as well as to variable input terminal V of the phase comparator 65 of PLL 60. The current phase signal .theta..sub.I derived from the comparator 80 is supplied to the phase comparator 82 as well as to a contact F of a switching circuit 83. The absolute voltage signal .vertline.V.vertline. derived from the absolute value detector 79 is supplied to a voltage comparator 84. The frequency characteristic of the absolute value of the voltage detection signal is shown in FIG. 7. In the voltage comparator 84, the absolute voltage value .vertline.V.vertline. is compared with a predetermined threshold value L, and the voltage comparator produces an output signal S when the absolute value is smaller than the threshold value L. Since the driving circuit of the present embodiment operates in the constant current mode, the absolute value of the

driving voltage represents the impedance of the ultrasonic (^) vibrating element 56. When the voltage comparator 84 generates the signal S, the phase comparator 82 is enabled to detect the phase difference .DELTA..theta. between the voltage phase signal .theta..sub.V and the current phase signal .theta.. sub.I. When the frequency of the driving signal becomes equal to the desired resonance frequency f.sub.r of the ultrasonic (^) vibrating element 56, the phase difference .DELTA..theta. becomes zero. Then, the phase comparator 82 generates a resonance detection signal R. This resonance detection signal R is supplied to a latch circuit 109 to change the state of the latch circuit 109. Then, the switching arm of the switching circuit 83 is changed from the contact S to the contact F and the current phase signal .theta..sub.I is supplied to the reference input terminal R of the phase comparator 65 and PLL 60 is operated in the feedback control mode in which the driving signal frequency is automatically controlled to follow the resonance frequency of the ultrasonic (^) vibrating element 56. At the same time, a light emitting diode 85 is lit to denote that PLL 60 is driven into the feedback control mode. It should be noted that the output signal derived from the latch circuit 109 is also supplied to a control circuit 93. The function of this control circuit 93 will be explained in detail hereinafter.

FIG. 8 is a circuit diagram illustrating a detailed construction of the phase comparator 82 and voltage comparator 84. The phase comparator 82 includes three D-flip-flops (D-FF) 89, 90, 91 and an OR gate 92. The voltage phase signal .theta..sub.V generated from the phase comparator 78 is applied to D-input of the first D-FF 89 and the current phase signal .theta..sub.I generated from the phase comparator 80 is applied to clock input CK of D-FF 89. Q and Q outputs of this D-FF 89 are applied to clock input CK of D-FF 90 and clock input CK of D-FF 91, and Q outputs of these D-FFs 90 and 91 are applied to the OR gate 92. An output signal from the OR gate 92 is supplied to the latch circuit 109 as the resonance point detection signal R. To D inputs of D-FFs 90 and 91 are applied a supply source voltage V.sub.CC. The voltage comparator 84 comprises a comparator IC 84a and the absolute voltage signal . vertline.V.vertline. derived from the absolute value detector 79 is applied to an inverted input of the operational amplifier and a variable voltage source 84b is connected to the non-inverted input. A voltage set by the variable voltage source 84b represents the threshold level L shown in FIG. 7. An output signal from the operational amplifier 84a is applied to clear terminals CLR of D-FFs 90 and 91.

As illustrated in FIGS. 6A and 6B, the absolute current signal . vertline.I.vertline. generated from the absolute value detector 81 is supplied to an inverted input of a differential amplifier 94. To a non- inverted input of the differential amplifier 94 is applied a preset signal generated fro ma current setting circuit 95. An output signal of the differential amplifier 94 is applied, via a limiter 96, to a control input terminal of the voltage controlled amplifier 71 to control the amplification factor thereof such that the ultrasonic (^) vibrating element 56 is always driven by the predetermined current which is set by the current setting circuit 98. To the current setting circuit 95 are connected a first variable resistor 97 for setting a higher driving current level and a second variable resistor 98 for adjusting a lower driving current level. The current setting circuit 95 is controlled by a control signal supplied from the control circuit 93 such that during the starting time period, the driving current is set to the lower current level and after PLL 60 has been driven into the feedback control mode, the driving current is increased into the higher current level. In the manner explained above, the absolute current value .vertline.I.vertline. is compared with the preset voltage supplied from the current setting circuit 95 in the differential amplifier 94 and the amplification factor of VCA 71 is controlled by the difference therebetween to control the driving signal to be applied to the buffer amplifier 72 and power amplifier 74. Therefore, even when the impedance is varied due to the variation in the load to the hand piece 55, it is possible to drive the ultrasonic (^) vibrating element 56 with the constant current having the value set by the current setting circuit 95, so that the vibration amplitude of the hand piece 55 can be maintained constant.

To the control circuit 93 is connected a trigger circuit 99 to generate a trigger signal under the control of the control circuit. The trigger signal is applied to a reference voltage generator 100 to generate a reference voltage signal having a sawtooth waveform. This sawtooth voltage signal is applied to an oscillator 101

formed by the voltage controlled oscillator to generate the reference signal .theta.. sub.ref having the monotonously increasing frequency. The frequency range of the oscillator 101 is substantially identical with that of VCO 68 in PLL 60.

FIG. 9 is a schematic view showing an example of the frequency ranges of the oscillator 101 and VCO 68. As shown in FIG. 9, the oscillator 101 and VCO 68 generate the signals whose frequency is varied from 22 KHz to 27 KHz. In FIG. 9 there are also illustrated the frequency and phase characteristics of two ultrasonic (^) vibrating elements. It should be noted that these ultrasonic (^) vibrating elements are designed to operate within a frequency range from 23 KHz to 26 KHz. In the starting period, the control circuit 93 sends a signal to the latch circuit 109 to reset it, and the switching circuit 83 is set by the latch circuit such that its switching arm is connected to the contact S. Therefore, the reference signal .theta..sub.ref is supplied to the reference input terminal R of the phase comparator 65 in PLL 60. The trigger signal generated by the trigger circuit 99 is also supplied to a counter 102 which counts the number of the trigger signals generated from the trigger circuit. When the counter 102 has counted a predetermined number of trigger signals, it produces an abnormal detection signal by means of which the switching circuit 73 is opened and a light emitting diode 103 is lit to indicate that any abnormal condition has occurred. It should be noted that the counter 102 is reset by a signal supplied from the control circuit 102 is reset by a signal supplied from the control circuit 93 when PLL 60 is changed from the sweep control mode to the feedback control mode.

The output signal from the loop filter (^) 67 in PLL 60 is also supplied to a low pass filter (^) (LPF) 104 to remove spike noise contained in the control voltage for VCO 68. The output of the low pass filter (^) 104 is applied to a window comparator 105. In the window comparator 105, the control voltage for VCO 68 is compared with lower and upper threshold levels, these threshold levels being corresponding to the lower and upper frequencies of the frequency range of the voltage controlled oscillator 68 as well as of the oscillator 101. That is to say, in the present embodiment, the lower threshold level of the window comparator 105 corresponds to 23 KHz and the upper threshold level corresponds to 26 KHz as can be understood from the drawing of FIG. 9. When the control voltage becomes lower or higher than the lower or upper threshold levels, the window comparator 105 sends a reset signal to the control circuit 93. Then, the control circuit 93 sends a reset signal to the trigger circuit 99 to generate the trigger signal, and at the same time, the control circuit 93 sends a reset signal to the latch circuit 109 to reset its condition. Therefore, the reference signal .theta..sub.ref is generated from the oscillator 101 and the switching circuit 83 is driven to selectively supply the reference signal to the phase comparator 65 in PLL 60. If the above explained resetting means is not provided, the oscillation frequency of VCO 68 is decreased or increased up to the lowest or highest frequency when the frequency of the driving signal becomes out of the automatic resonance frequency tracking range. In the present embodiment, the out-of lock condition is detected by the window comparator 105 and as soon as the driving frequency becomes out of the frequency range of the ultrasonic (^) vibrating element 56, PLL 60 is changed into the sweep control mode. The control voltage applied to the control terminal of VCO 68 is smoothed to a certain extent by the loop filter (^) 67, but when use is made of the edge trigger type phase comparator 65 and the loop filer must be designed to have the relatively high speed characteristic, so that the control voltage to be applied to VCO 68 might contain spike noise at edges of the two input signals to the phase comparator 65. This spike noise might affect the operation of the window comparator 105. In the present embodiment, such a spike noise can be removed by the low pass filter (^) 104.

To the control circuit 93 there are further connected a foot switch 106, a suction unit 107 for sucking body tissues cut by the ultrasonic surgical (^) knife, and a water supply unit 108 for cooling the probe 57 coupled with the hand piece 55 as well as for washing the cut portion of the body.

The absolute value of the .vertline.V.vertline. of the voltage detection signal supplied from the absolute value detecting circuit 79 is also supplied to a voltage comparator 86 and is compared with a

predetermined preset value to detect the impedance .vertline.Z.vertline.. The output of the voltage comparator 86 is used to selectively operate either one of light emitting diodes 87 and 88 which represent the short probe and the long probe, respectively. The output of the voltage comparator 86 is also used to control the matching switch operation in the select circuit 63. It should be noted that the above mentioned preset value in the voltage comparator 86 is determined such that the short probe 57 can be distinguished from the long probe 58 in a reliable manner.

Now the operation of the **ultrasonic surgical (^)** knife according to the present embodiment will be explained in detail.

As long as the foot switch 106 is made off, the switch 73 is opened and the switching circuit 83 is driven such that the switching arm is connected to the contact S so that the reference signal generated from the oscillator 101 will be supplied to the reference input terminal R of the phase comparator 65 in PLL 60.

When the operator pushes down the foot switch 106 with his or her foot to enter the start signal to the control circuit 93, the control circuit resets the latch circuit 109 and counter 102 and sends the selection signal to the current setting circuit 95 to select the lower constant current setting variable resistor 98, so that the current setting circuit applies the lower current setting voltage to the differential amplifier 94. At the same time, the control circuit 93 sends the control signal to the switch 73 so that the switch is closed. Furthermore, the control circuit 93 supplies the reset signal to the trigger circuit 99 to generate the trigger signal. Then, the reference voltage generator 100 starts to generate the sawtooth shape reference voltage and the oscillator 101 starts to generate the reference signal . theta..sub.ref having the frequency which is increased linearly. This reference signal .theta..sub.ref is supplied to the reference input terminal R of the phase comparator 65 by means of the switching circuit 83. At the same time, the voltage phase signal .theta..sub.V generated from the comparator 78 is applied to the variable input terminal V of the phase comparator 65. After the phase lock loop 60 has been driven into the phase lock condition, it operates to sweep the driving frequency in accordance with the linearly varying frequency of the reference signal .theta..sub.ref.

As explained above, in the sweep control mode, the current setting circuit 68 operates to generate the lower current setting voltage, so that the amplitude of current of the driving signal is maintained to the predetermined lower level. The impedance of **ultrasonic (^)** vibrating element 36 is proportional to the voltage of the driving signal, because the **ultrasonic (^)** element is driven under the constant current mode. The variation of the driving signal voltage is detected by the voltage-current detecting circuit 75, differential amplifier 76 and absolute value detector 79 and is monitored in the voltage comparator 84 and is compared with the predetermined threshold level L. The absolute voltage value .vertline.V.vertline. is also supplied to a voltage comparator 86 and is compared therein with a predetermined value to detect the probe 57 connected to the hand piece 55. During the first scan the output signal from the voltage comparator 86 is supplied to the select circuit 63 to change the connection of the primary windings 61-1 and 61-2 of the matching transformer 59. In this manner the output impedance of the driving circuit is matched to the impedance of the **ultrasonic (^)** transducer having the hand piece 55 including the **ultrasonic (^)** vibrating element 56 and the probe 57 coupled to the hand piece. At the same time, one of light emitting diodes 87 and 88 is lit to indicate the probe 57 coupled to the hand piece 55.

During the second scan, when the absolute value of the driving voltage .vertline.V.vertline. becomes smaller than the threshold level V. sub.SET, i.e. the impedance of the **ultrasonic (^)** vibrating element 56 is reduced lower than the predetermined value, the enabling signal S is supplied to the phase comparator 82 and the phase comparator is allowed to compare the phases of the voltage and current phase signal .theta.. sub.V and .theta..sub.I with each other. When the driving signal becomes in-phase with the resonance vibration of the **ultrasonic (^)** vibrating element 56, the phase difference between these signals becomes zero and the phase comparator 82 generates the resonance point detection signal R. Then, the latch circuit

109 is set by this signal and the output signal of the latch circuit 109 is supplied to the switching circuit 83 to change the switching arm from the contact S to the contact F, so that PLL 60 is driven to operate in the feedback control mode. At the same time, the light emitting diode 85 is lit by the output of the latch circuit 109. The latch circuit 109 also sends, to the control circuit 93, the signal which represents that the driving frequency has been locked with the desired resonance frequency f.sub.r of the **ultrasonic (^)** vibrating element 56. In response to this, the current setting circuit 95 is controlled to select the higher current setting variable resistor 97 and the higher current level setting voltage is applied to the differential amplifier 94, so that the current of the driving signal is adjusted to the predetermined higher level. Since PLL 60 operates in the feedback control mode, the frequency of the driving signal is automatically adjusted to the resonance frequency f.sub.r of the **ultrasonic (^)** vibrating element 56. When PLL 60 is driven into the feedback control mode, the control circuit 93 supplies the control signals to the suction unit 107 and water supply unit 108 and the desired operation is performed. Since this operation has been known in the relevant art of technique, its detailed explanation is dispensed with. The above operation is continued until the foot switch 106 is made off. It should be noted that the transfer into the resonance point tracking mode is effected even if the impedance change is not carried out by the select circuit 63 during the first scan.

If the resonance point is not found during the second frequency sweep, the frequency of the output oscillation of VCO 68 will be increased up to the maximum frequency of 27 KHz or will be decreased to the lowest frequency of 22 KHz of the frequency range of VCO 68 and oscillator 101. In the present embodiment, the frequency control voltage produced from the loop **filter (^)** 67 in PLL 60 is monitored by the window comparator 105, and when this voltage becomes higher than the upper threshold value corresponding to the maximum frequency of 26 KHz or the minimum frequency of 22 KHz of the frequency range of the **ultrasonic (^)** vibrating element 56, the window comparator 105 supplies the reset signal to the control circuit 93, so that the trigger circuit 99 is driven again. Then, the oscillator 101 restarts the generation of the reference signal .theta..sub.ref having the varying frequency to effect the frequency sweep again. In this manner, the frequency sweep operation is repeated until the driving signal is locked with the resonance frequency of the **ultrasonic (^)** vibrating element. The number of the reset operations is counted by the counter 102, and if the count value reaches a predetermined value such as ten, the switch 73 is forcedly made off and the light emitting diode 103 is lit to indicate that the driving signal could not be locked with the resonance frequency of the **ultrasonic (^)** vibrating element 56. Then, the operator can know that any abnormal condition has occurred in the hand piece 55. In this manner, it is possible to avoid any danger which might be produced when the **ultrasonic (^)** vibrating element 56 is continued to be driven under the abnormal condition.

According to the **ultrasonic surgical (^)** knife explained above, the kind of the probe coupled with the hand piece can be automatically detected and the impedance matching is effected also automatically, so that the hand piece can be driven always efficiently. Furthermore, the **ultrasonic (^)** transducer can be positively driven into the resonance point tracking mode, and even if the tracking mode is lost, it is possible to effect the restart. Moreover, the abnormal condition of the hand piece 55 can be detected. In the present embodiment, there is provided the constant current driving circuit, and thus the **ultrasonic (^)** vibrating element can be driven at the constant amplitude and the frequency characteristics of impedance can be detected in a simple manner, so that the resonance point can be detected accurately and positively. Further the voltage applied to the **ultrasonic (^)** vibrating element 56 and the current passing through the element are detected in the differential manner, so that the in-phase noise can be removed effectively and the desired voltage and current can be detected in regardless of the output type of the power amplifier 74. Therefore, the high tension circuitry surrounding the power amplifier can be floated with respect to the ground and the leakage current to the ground in the circuit of the **ultrasonic (^)** transducer can be reduced to a large extent.

It should be noted that the voltage applied to the **ultrasonic (^)** vibrating element and the current flowing through the element are detected on the primary side of the matching transformer 59 but they may be

detected on the secondary side of the matching transformer. Further, the amplitude which is adjusted by means of the variable resistor 97 in the current setting circuit 95 may be set by other means. For instance, as shown in FIG. 10, there may be provided maximum and minimum value setting circuits 110 and 111 for the short probe 57 and maximum and minimum value setting circuits 112 and 113 and these circuits may be selected by a relay 114 in accordance with the output of the voltage comparator 86. In this modified embodiment, the probes 57 and 58 may have different withstanding properties.

In the above explained embodiment, the impedance of two probes 57 and 58 is detected and the output impedance of the driving circuit is adjusted in accordance with the detected probe. According to the present invention, more than two probes may be detected to attain the proper impedance matching. In this case, there are arranged more than two taps on the primary side of the matching transformer 59 as shown in FIG. 11. These taps may be selected by relays 117-1 and 117-2 in accordance with the impedance of the ultrasonic (^) vibrating element detected by an impedance detecting circuit 115.

In order to protect the relay contacts for changing the primary windings of the matching transformer 59, the voltage applied to the ultrasonic (^) vibrating element 56 is reduced to zero upon the switching as explained before with reference to FIG. 3. It is also possible to insert a spark killer formed by CR circuit which does not affect within the driving frequency range between the contacts of the relay. Moreover, not only attain the impedance matching but also the frequency of the driving signal, an amount of supply water and so on may be changed in accordance with the detected impedance of the ultrasonic (^) vibrating element. Further, the present invention may be equally applied to various kinds of ultrasonic (^) devices such as ultrasonic (^) working machine other than the ultrasonic surgical (^) knife.

The present invention also relates to the ultrasonic (^) oscillation generating apparatus in which the ultrasonic (^) vibrating element can be driven stably and safely without breaking the driving circuit and ultrasonic (^) vibrating element and subjecting the living body to danger. In the ultrasonic (^) oscillation generating apparatus according to the invention, in order to attain the above object, there is provided a limiter for limiting the maximum amplification factor of the voltage controlled amplifier which is controlled in accordance with the driving current.

FIG. 12 is a block diagram showing the basic construction of the ultrasonic (^) oscillation generating apparatus according to the present invention, in which the maximum amplification factor is limited. An output of an oscillator 121 is supplied to a voltage controlled amplifier (VCA) 122 whose amplification factor can be varied. The output of VCA 122 is amplified by a power amplifier 123 and is then supplied to an ultrasonic (^) vibrating element 124. The ultrasonic (^) vibration produced by the ultrasonic (^) vibrating element 124 is transmitted to a probe 125. A current passing through the ultrasonic (^) vibrating element 125 is detected by a current detector 126 and an output of the current sensor is supplied via low pass filter (^) (LPF) 127 and voltage limiter 128 to VCA 122 as the amplification factor control signal.

FIG. 13 is a circuit diagram illustrating the detailed construction of a major part of the apparatus shown in FIG. 12. The power amplifier 123 comprises a differential amplifier 123-1 and a push- pull amplifier having two transistors 123-2 and 123-3. To inputs of the differential amplifier 123-1 are supplied the output of the oscillator 121 and the output of the power amplifier 123, and the output of the differential amplifier 123-1 is supplied to the bases of the transistors 123-2 and 123-3. The output of the power amplifier 123 is derived from the commonly connected emitters of the transistors 123-2 and 123-3 and is supplied via a matching transformer 129 to the ultrasonic (^) vibrating element 124. The current sensor 126 comprises a transformer 126-1 and a differential amplifier 126-2 for detecting the absolute value of the output of the transformer 126-1. The output of the differential amplifier 126-1 is supplied to LPF 127.

The low pass filter (^) 127 comprises a differential amplifier 127-1 to whose inverted input is supplied the output of the differential amplifier 126-2 via a resistor 127-6, a capacitor 127-2 and a resistor 127-3

connected in parallel with each other across the output terminal and the non-inverted input terminal of the differential amplifier 127-1, and a variable reference voltage supply source 127-5 connected to the non-inverted input terminal of the differential amplifier 127-1 via a resistor 127-4. The reference voltage supply source 127-5 is provided for setting the driving current for the ultrasonic (^) vibrating element to a given level. The output of the differential amplifier 127-1 is supplied to the voltage limiter 128.

The voltage limiter 128 includes a zener diode 128-1 having a given threshold voltage which limits the maximum level of the output voltage of the limiter 128 so that the maximum amplification factor of VCA 122 can be limited by the threshold voltage of the zener diode 128-1. That is to say, the amplification factor of VCA 122 can be adjusted within a range below the maximum level such that the driving current for the ultrasonic (^) vibrating element is made identical with the value set by the reference voltage supply source 127-5 in LPF 127.

By constructing the apparatus as explained above, even if the driving current for the ultrasonic (^) vibrating element 124 is reduced to a great extent and the output of LPF 127 is varied largely in accordance with the change in the electric property of the ultrasonic (^) vibrating element due to the variation of the object to which the tip of the probe 125 is urged, the amplification factor of VCA 122 is not increased extraordinarily, because the control voltage for VCA 122 is limited by the voltage limiter 128. Therefore, the driving circuit and ultrasonic (^) vibrating element can be effectively prevented from being applied extraordinarily high voltages which might cause the breakage of these parts. Further, the patient can be protected against the danger and injure, and the ultrasonic (^) vibrating element 124 can be operated stably and safely.

FIG. 14 is a block diagram depicting another embodiment of the ultrasonic (^) oscillation generating apparatus according to the present invention. In this embodiment, the impedance of the probe 125 detachably coupled with the ultrasonic (^) vibrating element 124 is detected by a probe identification circuit 131 for detecting a kind or type of the probe 125 in accordance with the impedance of the ultrasonic (^) vibrating element 124 and the maximum amplification factor of VCA 122 is adjusted by a voltage limiter 132 which is constructed to change the threshold value. The remaining construction of the apparatus according to the present invention is the same as the embodiment shown in FIG. 13.

FIG. 15 is a circuit diagram showing the detailed construction of the probe identification circuit 131 and voltage limiter 132 shown in FIG. 13. The probe identification circuit 131 comprises an impedance detecting circuit 133 for detecting the impedance of the probe 124, comparators 134-1 to 134-3 whose positive input terminals are connected to the output terminal of the impedance detecting circuit 133 and whose negative input terminals are connected to a supply source voltage V, NOT gates 135-1 and 135-2 and AND gates 136-1 and 136-2. In the present embodiment, the ultrasonic (^) vibrating element is driven by the constant current, so that the impedance detecting circuit 133 may be composed of a voltage detecting circuit. The voltage limiter 132 comprises three switches 137-1 to 137-3 connected in parallel with each other, and three zener diodes 138-1 to 138-3 connected in series with respective switches. It should be noted that the zener diodes 138-1 to 138-3 have different threshold voltages. When the impedance of the ultrasonic (^) vibrating element is high, all the comparators 134-1 to 134-3 produce outputs, so that the AND gates 136-1 and 136-2 do no generate the outputs. Therefore, only the switch 137-1 is closes and the zener diode 138-1 is connected to the output terminal of LPF 127. When the impedance of the ultrasonic (^) vibrating element is low, only the comparator 134-3 generates the output, so that only the switch 137-3 is closed and the zener diode 138-3 is connected to LPF 127. When the ultrasonic (^) vibrating element has the impedance which is between said high and low values, the comparators 134- 2 and 134-3 produce the output and the AND gate 136-1 actuates the switch 137-2 and the zener diode 138-2 is connected to LPF 127. In this manner, the maximum voltage applied to the control terminal of VCA 122 can be changed in accordance with the impedance of the ultrasonic (^) vibrating element.

FIG. 16 is a side view showing the detailed construction of the hand piece and the probe coupled thereto. The ultrasonic (^) vibrating element 143 is secured to a main body 142 of the hand piece 141. To the main body 142 is secured a hone 144 for amplifying the vibration of the ultrasonic (^) vibrating element and a flexible tube 145 is connected to the hone. Within the tube 145, there is formed a conduit 146 which is communicated with a suction tube 147 via the hand piece 141. The tube 145 is installed in a flexible insertion tube 148 of the endoscope. At the proximal end of the insertion tube 148 are provided a handle section 149 and a slider 150, and the tube 145 is secured to the slider 150. The slider 150 is biased by a spring 151 to move away from the handle section 149. By moving the slider 150 toward the handle section 149 against the force of the spring 151, the distal end of the tube 145 is protruded from the tip of the insertion tube 148 and is brought into contact with the tissues of a body to be processed. Within the insertion tube 148, there is also arranged an optical observing device including light guide optical fiber bundle, objective lens system and image guide optical fiber bundle, and an eye piece 152 coupled with the image guide fiber bundle is provided at the proximal end of the insertion tube 148.

By using the above explained apparatus, the object to be processed is observed by the endoscope and the tip of probe 145 is urged against the object, and then the ultrasonic (^) vibrating element 143 is driven to produce the ultrasonic (^) oscillation. The object is broken by the ultrasonic (^) vibration into pieces and the tissues are taken out of the patient body by means of the conduit 146.

It should be noted that the present invention can be applied not only the above explained ultrasonic (^) suction apparatus, but also the ultrasonic surgical (^) knife and ultrasonic (^) working apparatuses.

Further, in the embodiments so far explained the kind of the probe coupled with the ultrasonic (^) vibrating element is identified by detecting the impedance of the probe. However, according to the invention the probe may be identified by various methods. For instance, the shape of the base portion of the probe which is coupled with the front end portion of the ultrasonic (^) vibrating element may be changed in accordance with the kind of the probe and this shape of the end portion of the probe may be detected by detecting resistors arranged on the front end surface of the ultrasonic (^) vibrating element or an optically readable member such as a bar code and a means for detecting or reading the shape or the mark may be provided in the front end portion of the ultrasonic (^) vibrating element.

As explained in detail, in the ultrasonic (^) oscillation generating apparatus according to the present invention, since there is provided the means for limiting the upper threshold value of the amplification factor of the voltage controlled amplifier which is controlled on the basis of the driving current for the ultrasonic (^) vibrating element, even if the electrical property of the ultrasonic (^) vibrating element is changed to a great extent and the signal for controlling the amplification factor of the voltage controlled amplifier is increased extraordinarily, the amplification factor is restricted to the predetermined maximum value so that the voltage applied to the ultrasonic (^) vibrating element is not increased and the driving circuit and the ultrasonic (^) vibrating element can be protected effectively. Further the object to be processed can be effectively prevented from being injured to be processed can be effectively prevented from being injured and the ultrasonic (^) vibrating element can be driven stably and safely.

Drawing Description

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A and 1B are schematic views showing the vibration mode of the known ultrasonic (^) oscillation generating circuit;

FIG. 2 is a block diagram illustrating the principal construction of the ultrasonic (^) oscillation generating

apparatus according to the invention;

FIG. 3 is a block diagram depicting a first embodiment of the **ultrasonic (^)** oscillation generating apparatus according to the invention;

FIG. 4 is a flow chart for explaining the generation of the apparatus shown in FIG. 3;

FIGS. 5A and 5B are graphs showing the frequency characteristic of the driving voltage;

FIGS. 6A and 6B are is a block diagram illustrating a second embodiment of the apparatus according to the invention;

FIG. 7 is a graph representing the relationship between the frequency characteristic of the driving voltage and the output of the voltage comparator;

FIG. 8 is a block diagram showing the construction of the phase comparator;

FIG. 9 is a graph showing the frequency range of the **ultrasonic (^)** vibrating element and the oscillator;

FIG. 10 is a block diagram illustrating a third embodiment of the apparatus according to the invention;

FIG. 11 is a block diagram depicting a fourth embodiment of the apparatus according to the invention;

FIG. 12 is a block diagram showing the basic construction of the **ultrasonic (^)** oscillation generating apparatus according to the invention, in which the amplitude of the driving signal is limited;

FIG. 13 is a block diagram showing an embodiment of the apparatus according to the invention;

FIG. 14 is a block diagram illustrating another embodiment of the apparatus according to the invention;

FIG. 15 is circuit diagram showing the detailed construction of a major part of the apparatus; and

FIG. 16 is a side view depicting the whole construction.

Claims

What is claimed is:

1. An apparatus for generating an **ultrasonic (^)** oscillation comprising:

an **ultrasonic (^)** transducer having an **ultrasonic (^)** vibrating element for producing an **ultrasonic (^)** oscillation and a probe for transmitting the oscillation produced by the **ultrasonic (^)** vibrating element;

a driving circuit for supplying a driving power to said **ultrasonic (^)** vibrating element;

an impedance matching means connected between said **ultrasonic (^)** transducer and said driving circuit for matching the output impedance of the driving circuit to the impedance of said **ultrasonic (^)** transducer;

an impedance detecting means for detecting the impedance of said **ultrasonic (^)** transducer to generate an impedance detection signal; and

controlling means for automatically controlling said impedance matching means in accordance with said impedance detection signal supplied from said impedance detecting means such that the output impedance of said driving circuit is matched to the impedance of said **ultrasonic (^)** transducer.

2. An apparatus according to claim 1, wherein said impedance matching means comprises a matching transformer having a plurality of primary windings and a secondary winding, said secondary winding being connected to the **ultrasonic (^)** transducer, a switching circuit for selectively connecting one of said primary windings between said driving circuit and said **ultrasonic (^)** transducer, and a control circuit for controlling said switching circuit in accordance with said impedance detection signal supplied from said impedance detecting means such that the output impedance of said driving circuit is matched with the impedance of the **ultrasonic (^)** transducer.

3. An apparatus according to claim 2, wherein said switching circuit comprises a relay driven by said control circuit.

4. An apparatus according to claim 1, wherein said impedance detecting means comprises a circuit for detecting a voltage of said driving power supplied to the **ultrasonic (^)** transducer for use in determining the impedance of the **ultrasonic (^)** transducer.

5. An apparatus according to claim 4, wherein said circuit for detecting the voltage of the driving power is provided on an input side of said impedance matching means.

6. An apparatus according to claim 5, wherein said driving circuit comprises a constant current supply source for supplying a constant current to vibrate said **ultrasonic (^)** vibrating element at a constant amplitude.

7. An apparatus according to claim 4, wherein said driving circuit comprises a constant current supply source for supplying a constant current to vibrate said **ultrasonic (^)** vibrating element at a constant amplitude.

8. An apparatus according to claim 7, wherein said constant current supply source is constructed to supply a first low constant current which is sufficiently low not to drive the **ultrasonic (^)** vibrating element during a time period in which said impedance detecting means detects the impedance of the **ultrasonic (^)** transducer and a second high constant current which is sufficiently high to drive the **ultrasonic (^)** vibrating element.

9. An apparatus for generating an **ultrasonic (^)** oscillation, comprising:

an **ultrasonic (^)** transducer having an **ultrasonic (^)** vibrating element for producing an **ultrasonic (^)** oscillation and a probe for transmitting the oscillation produced by the **ultrasonic (^)** vibrating element;

a driving circuit for supplying a driving power to said **ultrasonic (^)** vibrating element;

an impedance matching means connected between said **ultrasonic (^)** transducer and said driving circuit and including at least two matching transformer means for matching the output impedance of the driving circuit to the impedance of said **ultrasonic (^)** transducer; and

controlling means for automatically controlling said impedance matching means such that the output impedance of said driving circuit is matched to the impedance of said **ultrasonic (^)** transducer.

10. An apparatus according to claim 9, wherein said controlling means comprises an impedance detecting means for detecting the impedance of said **ultrasonic (^)** transducer to produce an impedance detection signal and a selection circuit for selectively connecting one of said at least two transformer means between said driving circuit and said **ultrasonic (^)** transducer in accordance with said impedance detection signal.

11. An apparatus according to claim 10, wherein said impedance detecting means comprises a voltage detection circuit for detecting a voltage of said driving power supplied to said **ultrasonic (^)** transducer and a judging circuit for determining the impedance of the **ultrasonic (^)** transducer in accordance with the voltage detected by said voltage detection circuit.

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US5406503

Control system for calibrating and driving ultrasonic (^) transducer

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Application No. 954693, **Filed** 19920930, **Issued** 19950411

Abstract: An electronic control system for determining the resonant frequency of and driving ultrasonic (^) transducers in a phacoemulsification probe used for ophthalmic surgery. The control system includes a voltage control led oscillator, power amplifier, power monitor, and automatic gain control circuit operating under the direction of command signals received from a microprocessor-based control console. The control system operates in a constant apparent power, direct drive mode with closed loop feedback maintaining the electrical power provided to the primary of a RLC transformer at the constant level requested by the command signals from the console. The frequency of the drive signal is held at the dominant resonant frequency of the ultrasonic (^) transducer which is being driven by the control system. This resonant frequency is determined via a calibration procedure performed when the probe is first attached to the control system. During this procedure a constant voltage drive signal is swept through a range of frequencies and the electrical power consumed by the transducer is measured and stored at selected intervals such as 100 Hertz increments. The resonant frequency is also determined in part by looking for the frequency at which maximum power is consumed by the probe. The stored data is also subjected to other tests to check that the peak is indeed a resonant frequency and that the probe has selected output power characteristics about this resonant frequency, thus helping to ensure that the probe is capable of operating satisfactorily when driven by the control system.

US.Class: 702106 073579 606034 702060 606038 604022

Int'l Class: G01H01108 A61B01739

US Patents Cited: 2947889 3517665 3629726 3772538 3990452 4168447 4169984 4371816 4587958 4633119 4634420 4635483 4861332 4867141 4886060 4903696 4966131 4989155 5001649 5113116

Foreign References: EP0229003 SU1413440

Related Data: 428354 19891027

eye using a vibrating probe which operates at a frequency above the audio range. It is a well- known and widely used surgical (^) procedure for disintegrating cataracts. The probe includes a hollow needle vibrating at ultrasonic (^) frequencies to shatter the cataract; the shattered debris are withdrawn through the hollow part of the needle. The needle is mounted in an instrument which sometimes is referred to as a phacoemulsification handpiece, phaco handpiece or phaco probe. A number of designs for such handpieces or probes are known, the most common of which utilize piezoelectric transducers to produce the vibrations of the needle at ultrasonic (^) frequencies. Aforementioned application Ser. No. 07/251,531 describes and claims one such phacoemulsification probe that is commercially available from the assignee of the present invention, namely Storz Instrument Company of St. Louis, Mo. (hereinafter "Storz").

FIGS. 1A and 1B illustrate the construction of the phaco probe disclosed in the aforementioned application Ser. No. 07/251,531. The probe 20 includes an ultrasonic (^) transducer 22 located between a reflector 24 and resonator 26. The transducer 22 includes an electrode 30, constructed of unhardened #01 carbon steel, and two piezoelectric crystals 32 and 34. The crystals 32 and 34 may be constructed, for example, of a modified lead zirconate titanate ceramic material, formed into rings, and silver coated for electrical conductivity. Materials of this type are marketed under the trade name PXE by the Electronic Components and Materials Division of North American Phillips Corporation. An electrical lug 36 fastened to the electrode 30, allows a connection to be made to a power supply. An insulating tube 40 fits within the bore of the transducer 30. The reflector 24 is fastened to the resonator 26 by a hollow threaded tube 42 which mates to the threaded regions 44 and 46 in the reflector and resonator respectively.

Both the hollow tube 42 and the resonator 26 are preferably constructed of 6AL-4V titanium. Reflector 24 is constructed of the #17 tungsten. The insulating sleeve 40 may be made of Teflon. To assemble the components shown in FIG. 1B into the completed assembly 20 shown in FIG. 1A, threaded tube 42 is first threaded into the resonator 26 until the end 52 is seated against the shoulder 56 in the resonator 26. Then the reflector 24 is threaded onto the tube 42 until the transducer is compressed the desired amount.

The phaco probe 20 shown in FIG. 1 may be used as follows. A phacoemulsification needle 28, known in the art, such as Model No. IA-145 available from Storz, is screwed into the threaded end 58 of resonator 26. In use, the needle 28 vibrates in a longitudinal mode by alternately compressing to a retracted position illustrated by solid lines in FIG. 1A and expanding to a extended position illustrated by phantom lines 60. The vibrational displacements, indicated by dimension 62, may be anywhere from about 0.001 inch to about 0.005 inch, depending upon the strength and frequency of the electrical drive signal applied to the transducer. The vibration of the needle nominally occurs at the oscillation frequency of the piezoelectric crystals 32 and 34, which are coupled to the needle 28 through the resonator 26. Curved region 66 of the resonator 26 acts as a horn in order to impedance-match the crystals with the needle 28. Resonator 26, as a whole, functions as a one-quarter wave length transmission line (at the crystal frequency) on which needle 28 acts as a load.

The crystals 32 and 34 in FIG. 1 are driven by a signal applied to the electrode 30 and the reflector 24. The application of an alternating current signal to the crystals 32 and 34 causes them to cyclically expand to the extended position shown by phantom lines 70 in exaggerated form in FIG. 1B, and then contract to the solid position also shown in FIG. 1B. This cyclic expansion and contraction applies mechanical pulses to the resonator 26 at the signal frequency. The vibrating needle 28, when brought near a cataract, causes the cataract to shatter. The shattered debris is withdrawn through the channel 72 of the probe 20 under the influence of a vacuum generated by vacuum source 74 that is attached to the connector 76 by conventional plastic tubing represented by line 78.

As is known in the art, it is possible to construct piezoelectric crystals of various different materials, each of which has a characteristic resonant frequency. The crystal transducer 22 used with the Storz phacoemulsification probes of the type shown in FIG. 1 require a driving signal frequency applied to

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Hz. Thus even with the closed loop system, it has proved difficult under actual conditions to achieve consistently the desired match up between the frequency of the input signal to section 104 and the actual instantaneous resonant frequency of the transducer/probe combination.

As is well known, it is beneficial, in terms of operating efficiency, to provide a driving signal to an **ultrasonic (^)** transducer at its nominal resonant frequency. It has also been determined that when there is a slight mis-match between the frequency of the input signal and the natural resonant frequency of the transducer/probe combination, the stroke length of the needle is varied even as the command voltage supplied on line 112 from the console remains constant. At times, this mis-match of frequencies can result in a noticeable change in the ability of the oscillating needle 28 to perform its function, such as shattering the cataract within the eye. An operating surgeon who notices this change in performance will tend to compensate for such variations by either increasing or decreasing the strength of the command signal as needed. However, it would be quite advantageous to have a phaco probe driving circuit which is capable of maintaining the stroke length substantially constant even as the resonant frequency of the transducer/probe combination changes on account of one or more of the aforementioned five factors so that the surgeon would not have to compensate manually for such changes.

In light of the foregoing observation, it is a first object of the present invention to provide a system and method for automatically determining the resonant frequency of an **ultrasonic (^)** transducer. A related object of the present invention is to provide a method for automatically checking whether an **ultrasonic (^)** instrument is in proper operating condition.

A second important object of the present invention is to provide a driving system for an **ultrasonic (^)** transducer/phaco probe combination which automatically maintains the needle stroke length constant for a constant input command from the user. Another related object of the present invention is to provide a method of driving an **ultrasonic (^)** transducer of an ophthalmic **surgical (^)** instrument by holding electrical power consumed by the transducer substantially constant for a desired level of power consumption through the use of closed loop feedback control.

SUMMARY OF THE INVENTION

In light of the foregoing objects, there is provided, according to a first aspect of the present invention, a method for automatically determining the resonant frequency of a **surgical (^)** instrument powered by an **ultrasonic (^)** transducer. This method comprises the steps of: (a) providing an alternating current electric driving signal during a substantially constant voltage level to drive the **ultrasonic (^)** transducer at any desired one of a number of frequencies within a given range of frequencies; (b) monitoring the electrical power consumed by the probe at different frequencies within the range of frequencies; (c) selecting an apparent resonant frequency within the range of frequencies by determining which frequency, out of those frequencies which were monitored, had the greatest electrical power from the driving signal consumed by the probe; (d) comparing the amount of power consumed at the apparent resonant frequency with amounts of power consumed by the probe at a first frequency below the apparent resonant frequency and at a second frequency above the apparent resonant frequency; and (e) deciding whether the apparent resonant frequency is the dominant resonant frequency of the probe at least in part based upon the results of the comparisons performed in step (d).

According to a second aspect of the present invention, there is provided a method for checking if an **ultrasonic (^)** transducer in a **surgical (^)** instrument is in proper operating condition. This method comprises the steps of: (a) providing an alternating current electric driving signal to the transducer in order to drive the transducer at any desired one of a number of frequencies within a given range of frequencies; (b) changing the frequency of the driving signal such that the driving signal operates at plurality of different frequencies spanning the range of frequencies; (c) monitoring the electrical power consumed by

The conceptual basis for the present invention is the belief that the electrical power consumption of an acoustic resonant transducer operating in a fundamental vibration mode is directly correlated to the vibration amplitude of the transducer. From a practical view point, a given population of acoustic transducers will have differing resonant frequencies and impedances. Therefore, one goal of the methods and control system of the present invention is to level out the performance of these transducers devices as measured by vibration amplitude. Since the acoustic resonator, for example the type shown in FIG. 1, may be used to mechanically drive a hollow phaco needle, the excursion of the needle tip, that is the cyclical stroke length, may be used to measure the performance of the entire phaco probe.

Previous phacoemulsification probe drive systems have used a variety of constant voltage or constant current circuit schemes. For example, the FIG. 2 phaco drive circuit described above used a constant voltage oscillator structure, where the availability of a drive signal depends directly on the compatibility between the probe's impedance characteristics and the probe's electrical interactions with both the amplifier output circuit and the feedback network. Accordingly, it is necessary to match the characteristics of the probe to be driven quite closely to the characteristics of the amplifier output circuit and feedback network.

In contrast the phaco drive system of the present invention operates in a constant power, direct drive mode. There is always a drive signal available. Further, the frequency of this drive signal is fixed based upon results of successfully completing a calibration routine. This routine or method is designed to find the fundamental resonant frequency of the phaco probe, and to ensure the compatibility between the probe power spectral characteristics and the driving circuit of the present invention.

These and other objects, advantages and aspects of the methods and drive system of the present invention may be further understood by referring to the detailed description, accompanying figures and dependent claims.

Detailed Description

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

FIG. 3 shows a simplified block diagram of the electronic control system 120 for determining the dominant resonant frequency of and for driving a phaco handpiece. The control system 120 includes: a microcomputer 122 having a processor 124, volatile (RAM) memory 125, nonvolatile (ROM) memory 126, and a control/address/data bus 128 communicating in conventional fashion with input ports 130 and output ports 132 and other portions of microcomputer 122; a voltage controlled oscillator ("VCO") section 134; a power amplifier section 136; a power monitor section 138; and an automatic gain control ("AGC") section 140. The control system 120 may also include a transformer section 142 for stepping up the voltage of the power drive signal delivered from the power amplifier 136 to the phaco handpiece 20. The microcomputer 122 provides a first desired power command signal (C.sub.p1) on signal path 148. frequency command signal (C.sub.F) on path 150 to the VCO section 134, and may optionally receive back an actual frequency signal (F.sub. A) on signal path 152.

VCO section 134 provides to signal path 154 an unamplified sinusoidal signal (V.sub.U) at the desired frequency whose amplitude is proportional to the desired power level specified by signal C.sub.p1. This signal is amplified by power amplifier section 136, and which produces an amplified sinusoidal power signal (V.sub.A) on line 156 which is supplied to the transformer section 142 and also to the power monitor section 138. Power amp section 136 also receives an error correction signal (E.sub.C) on line 160 from AGC section 140. AGC section 140 receives a second desired power level command signal (C.sub. P2) on path 162, and a control signal on path 163 from microcomputer 122, and receives a monitored power level signal (M.sub.P) on line 168 from power monitor section 138. The power monitor section

the electrical power consumed by the probe 20. The processor 124 fills a table in memory 125 with ordered pairs consisting of signal frequencies and load power information. Several tests are performed on this data, which will be described later below, which ensure a minimum compliance of the curve representing the acquired data against: standard curve for an ideal ultrasonic (^) transducer/probe combination. Certain variances from the standard curve indicate specific types of failure conditions existing in the phaco handpiece 20, such as open or short circuits, missing or loose needles, and excessively damped transducers. These tests will also fail if the wrong transducer type is connected to the transformer section 142.

If the initial calibration procedure is successful, the processor 124 will store the frequency at which the load power was at a maximum. That single frequency will then be used when driving the phaco handpiece 20 until such time as the next phaco calibration sequence is performed. After calibration, the outer control loop Just described is opened, and the inner control loop is engaged.

The inner control loop uses the automatic gain control section 140 as well as sections 136, 138 and 142. When the inner control loop is to be engaged, an appropriate control signal is provided on path 163, which enables an automatically determined error correction signal on line 160 to be provided to the power amplifier section 136.

The operation of the automatic gain control section 140 may be summarized as follows. When the processor 124 commands a specific percent power level via signal C.sub.P2 on path 162, an analog reference voltage is generated internally with the AGC section 140. The voltage representing load power on line 168 is compared to this reference voltage and the difference is integrated in the hardware of the AGC section 140. The output of an internal integrator circuit is provided as the error correction signal E.sub.C on line 160, and drives the gate of a field effect transistor ("FET") located in power amplifier section 136. The channel resistance of this FET provides a shunt path to ground for the desired power level command signal V.sub.U provided on line 154. The larger the channel resistance of the FET, the stronger the power signal provided to drive the probe 20. The result of the operation of the closed loop is that the amplitude of the power signal on line 156 is constantly changing to match the changing impedance characteristics of the probe 20.

FIG. 4 shows a detailed block diagram of the control system 120 shown in FIG. 3, except for the microcomputer system 122. In particular, FIG. 4 shows all of the functional hardware components which constitute part of the driving circuitry of control system 120. The major blocks shown in FIG. 3 are shown in dashed lines in FIG. 4 to facilitate comparison between FIGS. 3 and 4. The components within the various blocks will be discussed, followed by an explanation of the interaction of the various sections.

VCO section 134 includes a digital-to-analog converter ("DAC") 210, a voltage controlled oscillator 212, pre-amplifier 214, a frequency counter 216 including a digital counter section 218 and control interface 220 and a second DAC 222. The first DAC 210 receives the frequency command signal on path 152 in digital form and converts it to a corresponding analog voltage on line 226 which inputs it into the oscillator 212. VCO 212 produces a sinusoidal output signal having a frequency corresponding to the applied input voltage. The design of the voltage controlled oscillator 212 is conventional, and may be designed to produce an output signal in a selected range of frequencies. In the preferred embodiment, the VCO 212 produces 35 kilohertz at the minimum input voltage and 21 kilohertz at the maximum input voltage V.sub.CC. DAC 210 and DAC 222 preferably have 12-bit resolution for 4,096 different possible output values. Pre-amplifier 214 strengthens and smoothes out the sinusoidal signal on line 228 to produce a fixed amplitude voltage signal (V.sub.F) on line 230. Signal V.sub.F is fed to the input of frequency counter 216 and to the voltage reference terminal of DAC 222.

Frequency counter 216 is used to check the output frequency of the VCO 212 in response to known values input to DAC 210 by signal path 152. Control signals delivered on path 232 from microcomputer 122 to

amount of power lost across resistor 302 represents well under 10% of the total power consumed by the probe 20, even under most low power conditions. Thus the amplifiers 310 and 312 could be omitted and the line 300 wired directly to the V.sub.X input of multiplier 320 if desired. However, for the sake of more accurate performance, the preferred embodiment includes amplifiers 310 and 312 as shown. The signal M.sub.P on line 168 is also supplied to 12-bit resolution ADC 175 which, as previously explained, outputs the digital value of the signal M.sub.P to microcomputer 122.

AGC section 140 includes signal interface 330, 12-bit resolution DAC 332, voltage amplifier 334 having a fixed gain G, multiplier 336, integrating difference amplifier 338 and analog switch 340, all connected as shown. Signal interface 330 conditions the control signal on line 163 from microcomputer 122 to produce the digital control signal 342. In one state, the signal on line 342 causes analog switch 340 to be nonconducting, thus blocking the output signal on line 344 from passing to line 160. In its other state, the control signal on line 342 causes analog switch 340 to be fully conducting, thus allowing the output signal of line 344 to pass freely to line 160. Those in the art will appreciate when analog switch 340 is rendered nonconducting by the signal on line 342, the AGC section 140 is effectively removed from the control system, as was described within the explanation of the calibration procedures above with respect to FIG. 3.

DAC 332 converts the digital C.sub.P2 on path 163 to an analog value V.sub.C2 on line 352. Signal V.sub.C2 is multiplied by G in amplifier 334 and passed to both inputs of multiplier 336. The resulting output signal on line 356 of multiplier 336 is thus proportional to the square of the input signal presented on line 354. The motivation for using the multiplier 336 in the AGC section 140 is that it effectively increases the dynamic range of AGC section 140 which not sacrificing much if anything in the way of accuracy. In the preferred embodiment, the digital value C.sub.P2 is proportional to the square root of the desired power level signal C.sub.P1, whose value is proportional to desired level of power communicated by the surgeon to the microcomputer 122. If multiplier 336 were not used, then, the signal C.sub.P2 would be directly proportional to the desired level of power, and the output of scaling amplifier 334 would be fed directly to the positive input of integrating difference amplifier 338. By providing the square root of the desired power signal as the digital value C.sub.P2 on path 162, the AGC section is provided with greater sensitivity at lower values of desired power, which can be advantageous from a user's point of view.

Difference amplifier 338 includes a feedback capacitor 358 so that AGC circuit thus employs both proportional and integral, while still providing feedback control. As is well known, integral feedback control has the beneficial tendency under steady-state loop conditions to drive the absolute errors in a closed loop feedback system to zero. In the preferred embodiment, the capacitor 358 is sized to have an RC time constant of approximately 35 to 100 milliseconds with about 50 to 65 milliseconds being preferred, and the amplifier 338 preferably has a gain of about one.

When the inner loop is engaged, the control system 120 shown in FIG. 4 continuously provides a driving signal V.sub.A on line 156 whenever the desired power level signals C.sub.P1 and C.sub.P2 are non zero. Further, the frequency of the driving signal when the probe 20 is in use is always set at the dominant resonant frequency of the transducer/probe combination, as determined by the calibration procedure, which will be more fully explained shortly. The effect of changes in the actual instantaneous resonant frequency of the combination of the probe 20 and its **ultrasonic (^)** transducer 22 is compensated for by the error signal E.sub.C produced by the AGC section 140, which automatically adjusts the effective gain of power amplifier section 136 as needed. As can be seen from the foregoing discussion of power monitor section 136 and AGC section 140, the actual electrical power consumed by the probe/transducer combination is compared against the desired power level to obtain the correction signal. For stability and in order to eliminate long-term offset errors in the closed loop system, difference amplifier 338 integrates the error signal on its output 344.

Those in the art should appreciate that the hardware shown in FIG. 4 does not monitor or otherwise take

FIG. 5 shows typical power transfer characteristics of an electronic amplifier or circuit, such as power amplifier section 136, designed to have an output impedance of 4 ohms. FIG. 5 shows a graph of the power consumed by various resistive loads when using a .+-.30 volt (peak) AC power source and a maximum signal voltage of .+-.27 volts (peak). As expected, the curve 380 has a portion 382 which rises as the load impedance increases from 1 ohms to 4 ohms, and a portion 384 which decreases as the load impedance changes from 4 ohms to 10 ohms. In order to make the power amplifier section 136 operate effectively over a relatively wide range of impedances from about 2 ohms to about 10 ohms, a power limit of 35 watts is imposed by design upon the performance of amplifier section 136, even though at 4.0 ohms it could, if unrestricted, deliver a maximum power of 90 watts. Limiting a power amplifier to a fixed upper power limit, such as 35 watts, is a well-known design technique for audio power amplifiers, and need not be described further here, other than to note that such techniques are used in power amplifier section 136 of the present invention.

In FIG. 5, the second and third sets of numbers below the horizontal axis are labeled Z.sub.PRI and Z.sub.SEC, and represent the primary and secondary impedances of the 30:1 step-up transformer 262.

FIGS. 6 and 7 help illustrate graphically the validity of the design concept of the present invention. FIG. 6 shows the variance in electrical power consumption between two distinct families of ultrasonic (^) transducers with the families having very different resonant frequencies. Curves 400, 402 and 404 represent the average power consumed by four transducers in one family from one commercial supplier (Southtown Machine Co. of St. Louis, Mo.) at power levels of 50%, 70% and 100% (where 100% =35 watts). This first family of transducers has a nominal impedance of 8.4 kilo-ohms and a resonant frequency of about 28.2 KHz. Curves 410, 412 and 414 represent the average power consumed by eight transducers from another commercial supplier (Lavezzi Precision, Inc. of Elmhurst, Ill.) at power settings of 50%, 70% and 100%. This second family of transducers had a nominal impedance rating of 4.2 kilo-ohms, and a resonant frequency in the range of 29.1 to 29.25 KHz. Thus, FIG. 6 shows that there is a tremendous variance in resonant frequencies and in electrical power consumption between two distinct populations of ultrasonic (^) transducers.

It would be very desirable to have a single phaco probe drive system that would operate phaco probes using transducers from either family successfully and without much if any variance in probe performance. The probe driving circuitry of the present invention does this. The differences between the peak power consumption and the resonant frequencies of the two populations of transducers is of no major concern. In order to have both families of transducers being successfully driven by the electronic control system of the present invention, then only the power amplifier selection and frequency band widths of the various sections of the control system need be selected and designed to operate over the desired range of frequencies. As may be seen from FIG. 5, the power amplifier section 136 is easily made to operate over a primary impedance range of 2.2 ohms through 10.4 ohms by simply limiting the maximum power produced by amplifier section 136 to an appropriate fraction of its peak power, such as about 35 percent as shown in FIG. 5.

In prior art driving systems for phaco probes, the difference in peak electrical power consumption between transducers populations is a major concern, particularly for drive systems employing a constant voltage strategy. In fact, the graphs in FIG. 6 were generated from a nearly constant voltage drive source. The input voltage to the power amplifier driving the RLC transformer section was constant, but there was no compensation circuitry to maintain the output voltage constant. So as the load impedance varied, so did the output voltage of the power amplifier because of the voltage divider relationship between the load impedance and source (output) impedance. This relationship is largely responsible for the power transfer characteristics shown in FIG. 6.

FIG. 7 demonstrates the similarities between transducer performance of the two populations of transducers

each one used must be met. First, the maximum power consumed by the probe at the apparent resonant frequency F. sub.AR must be greater than or equal to a predetermined power level, such as 12 watts. Second, the frequency F.sub.AR must fall between 27 kilohertz and 31.5 kilohertz. Third, the half-power band for the transducer/probe must be less than or equal to 1,000 Hz. In other words, at 0.5 KHz above and at 0.5 KHz below the frequency F.sub.AR, the power consumed by the transducer/probe must be less than or equal to one-half of the maximum power consumed (F.sub.Pmax) at the frequency F.sub.AR. The fourth criterion which must be satisfied is that the consumed power at each of a selected number of readings below and closest to the frequency F.sub.AR, and each of the readings at a selected number of readings above the frequency F.sub.AR must monotonically decrease with increasing distance from F.sub.AR. The selected number of readings is preferably five. A fifth criterion is also preferably employed. This criterion requires that all readings more than 500 Hz away from the frequency F.sub.AR be less than or equal to a predetermined fractional value of P.sub.max, such as less than 50% of P.sub.max.

The software used in microcomputer 122 which implements the calibration procedures mentioned above and operates control system 120 in the following manner (See FIGS. 3 and 4). During the initialization of the microcomputer 122, the VCO section 134 is interrogated to determine its response under minimum and maximum conditions in order to verify that it is operational and to determine its frequency response. The signal applied to the VCO is simply a DC voltage signal which varies from 0 to 5 volts, and which is produced by a DAC 210. Frequency counter 216 is used to determine the frequency of the output signal being produced by VCO 212. Frequency counter 216 is digitally interrogated by the microprocessor 124 as previously explained with respect to FIG. 4, in the following manner.

The minimum condition or zero volts signal on line 226 is represented by all zeros in the 12-bit word C.sub.F sent to DAC 210 and the frequency output produced by VCO 212 is then determined. Normally it is about 35 KHz. Then, the maximum condition, namely, all ones in the 12- bit word C.sub.F is sent to the DAC 210 and the output frequency of the VCO 212 in response thereto is counted and reported by the frequency counter 216. (The VCO 212 is assumed to have a linear response between the two values tested for.)

The calibration procedure employed to determine the dominant resonant frequency F.sub.DR of the transducer/probe combination has two phases, a "coarse" phase and a "fine" phase. The output of the power amplifier section 136 is run at a 50% level for all steps of the coarse phase and fine phase. During the coarse phase, the following steps take place. The desired frequency of the probe is assumed to be somewhere between 27.0 KHz and 31.5 KHz. To assure that appropriate readings are taken, the frequency of the VCO is swept from 26.5 KHz up to 32.0 KHz. During the coarse phase, the frequency is incremented by 100 Hz with each successive power reading taken. At each 100 Hz increment from 26.5 KHz to 32 KHz, the (apparent) electrical power consumed by the probe is read by the power monitor section 138 and stored in RAM 125 of microcomputer 122. At the end of this coarse sweep, one of these readings will be the highest and is designated P.sub.max, and its associated frequency will be presumed the apparent resonant frequency F. sub.AR.

Next, the frequency F.sub.AR is checked in several ways to determine whether it is a true or dominant resonant frequency, and whether the **ultrasonic (^)** transducer within the probe appears to be working properly. First, the frequency peak is checked to make sure it is within 27.0 to 31.5 KHz. Second, the peak amplitude P.sub.max must be above a predetermined minimum, such as 12 watts. (This minimum will be a function of the power level applied to the probe during the coarse sweep, and will normally be some value such as 65 or 75 percent of the sweep power level.) Third, for the five closest readings to and below frequency F.sub.AR, and the five closest readings to and above frequency F.sub.AR, each consumed power level must monotonically decrease from P. sub.max with increasing distance from the frequency F.sub.AR. Fourth, the lower and upper power half-bands must occur respectively within F. sub.AR -500 Hz, and F.sub.AR +500 Hz. That is to say, the power consumed at F.sub.AR -500 Hz and at F.sub.AR +500 Hz

FIG. 3 is a simplified block diagram of the electronic control system of the present invention for calibrating and driving an **ultrasonic (^)** transducer used in a phaco handpiece of the general type shown in FIG. 1;

FIG. 4 is a detailed block diagram of the FIG. 3 control system showing the various functional components of the electronic hardware thereof.

FIG. 5 is a graph illustrating the power transfer characteristics of the power amplifier section of the FIG. 3 control system, and how they can be utilized to apply a constant power limit to phaco probes having wide range of input impedances;

FIG. 6 are two sets of graphs showing the output power versus input frequency response characteristics or curves obtained from two different types of phaco probes driven at 50, 70 and 100 percent power levels by a 35 watt power amplifier set up to drive a 6 kilo-ohm load;

FIG. 7 shows the output stroke versus percent power command characteristics of the phaco probes used to generate the FIG. 6 graphs when such probes are driven by the electronic control system of the present invention; and

FIG. 8 is an annotated graph showing a prototypical output power versus input frequency curve for a phaco probe, which helps illustrate the calibration method of the present invention used to qualify phaco probes and determine their resonant frequency.

Claims

We claim:

1. A method for automatically determining the resonant frequency of a **surgical (^)** instrument powered by an **ultrasonic (^)** transducer, and for driving the transducer to automatically maintain constant power output, comprising:

providing an alternating current electric driving signal having a substantially constant voltage amplitude to drive the **ultrasonic (^)** transducer at each of a plurality of frequencies;

monitoring electrical power consumed by the instrument by measuring voltage applied to and current drawn by the instrument at each of said plurality of frequencies;

selecting a dominant frequency by determining which frequency, out of those frequencies which were monitored, had the greatest electrical power consumed by the instrument;

setting the driving signal at said dominant frequency; and

driving the **ultrasonic (^)** transducer at said dominant frequency while automatically varying the voltage amplitude of the driving signal to maintain substantially constant power output independent of changing conditions experienced by the instrument.

2. A method for automatically determining the resonant frequency of a **surgical (^)** instrument powered by an **ultrasonic (^)** transducer, and for driving the transducer to maintain constant power output, comprising the steps of:

providing an alternating current electric driving signal having a substantially constant voltage amplitude to drive the **ultrasonic (^)** transducer at each of a plurality of frequencies within a given range of frequencies;

resonant frequency with amounts of power consumed by the instrument at frequencies below the apparent resonant frequency, and at frequencies above the apparent resonant frequency, where the frequencies are a successively greater incremental distance from the apparent resonant frequency, and comparing the power consumed at the instrument with a predetermined value.

8. A method as in claim 7, wherein:

said pluralities of frequencies are within a band of frequencies from about 26 KHz to about 32 KHz;

the first and second frequencies are at least about 100 Hz from the apparent resonant frequency.

9. A method as in claim 2, wherein:

said plurality of frequencies is within a band of frequencies from about 26 KHz to about 32 KHz; and

the first and second frequencies are at least about 100 Hz from the apparent resonant frequency.

10. An electronic control system for determining the dominant resonant frequency of an ophthalmic surgical (^) instrument containing an ultrasonic (^) transducer and for thereafter driving said transducer at its dominant resonant frequency for a constant power output at a specified power level comprising:

means for producing an alternating current ("AC") electrical signal at each of a plurality of frequencies to power the ultrasonic (^) transducer;

means for monitoring electrical power consumed by the transducer from the AC electrical signal at each of said plurality of frequencies;

means for selecting an apparent resonant frequency by determining which frequency within the range of frequencies is the dominant resonant frequency under test conditions;

drive means for generating an AC electrical signal at the selected apparent resonant frequency and for delivering said electrical signal to said transducer; and

automatic closed loop feedback control means, responsive to the means for monitoring, for adjusting the voltage amplitude of the AC electrical signal produced by said drive means to maintain the power consumed by the ultrasonic (^) transducer at a substantially constant level substantially independent of changing conditions experienced by the instrument hen the to substantially continuously achieve the specified power level.

11. The apparatus of claim 10, further comprising:

means for determining whether the frequency at which the transducer appears to consume maximum power is a true peak frequency relative to at least one adjacent frequency above and at least one adjacent frequency below said apparent resonant frequency.

12. An apparatus as in claim 10, wherein:

the drive means includes means for producing electrical signals having a first signal representative of a desired power level;

the means for monitoring includes means for producing a power feedback signal representative of the